Supreme Court, U.S.
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No.

IN THE
Supreme Court of the United States

ELI LILLY & CO.,

Petitioner,

v.

BOARD OF REGENTS OF THE
UNIVERSITY OF WASHINGTON,

Respondent.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

PETITION FOR WRIT OF CERTIORARI

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January 13, 2004

QUESTION PRESENTED

Can the Federal Circuit allow the U.S. Patent and Trademark Office to issue two patents, both claiming the same invention, without determining who was the first to invent?

PARTIES TO THE PROCEEDING BELOW

Eli Lilly & Company and the Board of Regents of the University of Washington were the parties to the proceedings below.

There are no corporations or publicly held companies that own 10 percent or more of the stock of Eli Lilly & Company and Eli Lilly & Company has no parent corporation.

TABLE OF CONTENTS

Page

QUESTION PRESENTED i

TABLE OF CONTENTS iii

TABLE OF AUTHORITIES vi

OPINIONS 1

JURISDICTION 1

CONSTITUTIONAL AND STATUTORY PROVISIONS 1

STATEMENT OF THE CASE 3

1. Lilly and UW Claim Genetic Sequences that Encode a Lifesaving Drug to Treat Severe Sepsis 3

2. The Interference 4

3. The Appeal 7

4. Petition for Rehearing 9

REASONS FOR GRANTING THE WRIT 9

I. The Majority's Holding Has Allowed More Than One Patent to Issue for the Same Invention 11

II. The Majority's Holding that Allows Two Patents for One Invention Conflicts with Federal Circuit Precedent Regarding Multiple Patent Claims 13

III. When Two Patents are Issued that Claim the Same Invention, the Public is Harmed, the Patent System is Harmed, and the Party with the Valid Patent Is Harmed 14

A. The Public Is Harmed Because There Is an Extension of the Term of Exclusivity from the Claimed Subject Matter 15

B. The Patent System As a Whole Is Harmed Because It Promotes Invalid Patents 15

C. Lilly Is Harmed Because It Has Lost a Constitutional Property Right and Has No Effective Legal Recourse 17

IV. The Majority Affirmed the Issuance of Two Patents for One Invention Because It Accorded the PTO with Deference Beyond What It Deserves 19

A. The PTO Exercised Its Discretion Only to Conserve Resources, Not to Further the Goals of the Patent System 20

B. The PTO Deserves Less Deference in this Case Because the "Two-Way Test" Is Not Longstanding 22

CONCLUSION.....24

TABLE OF AUTHORITIES

FEDERAL CASES

Aelony v. Arni,
547 F.2d 566 (C.C.P.A. 1977) 10, 12

Antos v. Juguin,
220 U.S.P.Q. 722 (Bd. Pat. Int. 1981) 23

Apotex USA, Inc. v. Merck & Co.,
254 F.3d 1031 (Fed. Cir. 2001) 10, 12

Barton v. Adang,
162 F.3d 1140 (Fed. Cir. 1998) 19, 20

Bowles v. Seminole Rock & Sand Co.,
325 U.S. 410 (1945) 19

Chevron U.S.A. Inc. v. Nat'l Res. Def. Council, Inc.,
467 U.S. 837 (1984) 19

Daniels v. Daum,
214 U.S.P.Q. 911 (Bd. Pat. Int. 1982) 23

Dickinson v. Zurko,
527 U.S. 150 (1999) 19

Eli Lilly and Co. v. Barr Laboratories, Inc.,
251 F.3d 955 (Fed. Cir. 2001) 10, 13, 14

Ewing v. U.S. ex rel Fowler Car Co.,
244 U.S. 1 (1917) 19

Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.,
535 U.S. 722 (2002) 13

Geneva Pharm. Inc. v. GlaxoSmithKline P.L.C.,
349 F.3d 1373 (Fed. Cir. 2003) 10, 13, 14

Good Samaritan Hospital v. Shalala,
508 U.S. 402 (1993) 24

Juicy Whip, Inc. v. Orange Bang, Inc.,
292 F.3d 728 (Fed. Cir. 2002),
cert. denied, 537 U.S. 1019 (2002) 11

Ex parte Kroekel,
230 U.S.P.Q. 191 (Bd. Pat. App. & Int. 1985),
aff'd, 803 F.2d 705 (Fed. Cir. 1986) 12

MCI Telecomm. Corp. v. American Tel. and Tel. Co.,
512 U.S. 218 (1994) 12

Ex parte McGrew,
41 U.S.P.Q.2d 2004 (Bd. Pat. App. & Int. 1995),
aff'd, 120 F.3d 1236 (Fed. Cir. 1997) 10

Medichem, S.A. v. Rolabo, S.L.,
No. 02-1461, -1480, slip op.
(Fed. Cir. Dec. 23, 2003) 18, 21

New Idea Farm Equip. Corp. v. Sperry Corp.,
916 F.2d 1561 (Fed. Cir. 1990) 12

Perkins v. Kwon,
886 F.2d 325 (Fed. Cir. 1989) 19

Public Citizen v. Nuclear Regulatory Comm'n,
901 F.2d 147 (D.C. Cir. 1990) 12

Ragsdale v. Wolverine World Wide, Inc.,
535 U.S. 81 (2002) 20

Ex parte Rapse,
156 U.S.P.Q. 217 (Bd. Pat. App. 1967) 17

Rust v. Sullivan,
500 U.S. 173 (1991) 24

Sakano v. Rutemiller,
158 U.S.P.Q. 47 (Bd. Pat. Int. 1968) 23

In re Slayter,
276 F.2d 408 (C.C.P.A. 1960) 6, 11

Titanium Metals Corp. of Am. v. Banner,
778 F.2d 775 (Fed. Cir. 1985) 6, 11

United States v. Larionoff,
431 U.S. 864 (1977) 12

Walker Process Equip., Inc. v. Food Mach. & Chem. Corp.,
382 U.S. 172 (1965) 18

Warner-Jenkinson Co. v. Hilton Davis Chem. Co.,
520 U.S. 17 (1997) 13

Winter v. Fujita,
53 U.S.P.Q.2d 1234 (Bd. Pat. App. & Int. 1999) 22

CONSTITUTION

U.S. Const., Art. I, § 8[8] 1, 15

FEDERAL STATUTES

28 U.S.C. § 1254(1) 1

35 U.S.C. § 101 12

35 U.S.C. § 102 ..... 2, 6, 10, 12, 18

35 U.S.C. § 103 ..... 2, 6, 10

35 U.S.C. § 135(a) 2, 7, 10, 19

35 U.S.C. § 291 18

REGULATIONS

37 C.F.R. § 1.601 ..... 2, 4, 5, 6, 7, 8, 9, 23

37 C.F.R. § 1.608 19

37 C.F.R. § 1.657(a) 4, 7, 11

49 Fed. Reg. 48,416 (Dec. 12, 1984) 23

65 Fed. Reg. 79,809 (Dec. 20, 2000) 20, 22

68 Fed. Reg. 66,648 (Nov. 26, 2003) 22

OTHER

FDA Press Release, November 21, 2001, available at http://www.fda.gov/bbs/topics/NEWS/2001/NEW00780.html. 3

To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy, 2003 WL 22507757 (F.T.C. October, 2003) 15, 16

Comment of the American Intellectual Property Law Association, available at http://www.uspto.gov/web/offices/dcom/bpai/rule/aipla.htm 22

Comment of the Intellectual Property Owners' Association, available at http://www.uspto.gov/web/offices/dcom/bpai/rule/ipo.htm 22

Comment of Genentech, Inc. available at http://www.uspto.gov/web/offices/dcom/bpai/rule/sjohnston.htm. 22

OPINIONS

The July 3, 2003, opinion of the court of appeals, which was reported at 334 F.3d 1264 (Fed. Cir. 2003), is set out at pp. 1-23 of the Appendix to this Petition. The June 11, 2002, opinion of The Board of Patent Appeals and Interferences, was reported at 2002 Pat. App. LEXIS 176 (Bd. Pat. App. & Int. Jun. 11, 2002), and is set out at pp. 24-70 of the Appendix. The October 15, 2003, order of the Court of Appeals for the Federal Circuit denying the petition for panel rehearing and rehearing en banc is set out as pp. 66-68 of the Appendix and is reported at 2003 U.S. App. LEXIS 22665 (Fed. Cir. Oct. 15, 2003).

JURISDICTION

The judgment of the Court of Appeals for the Federal Circuit was entered on July 3, 2003, and a denial of Appellant's Petition for Panel Rehearing and Rehearing En Banc was entered on October 15, 2003. The jurisdiction of this Court is invoked under 28 U.S.C. § 1254(1).

CONSTITUTIONAL AND STATUTORY PROVISIONS

Article I, sec. 8[8] (in relevant part)

> The Congress shall have the Power . . . [8] to promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors exclusive Right to their respective Writings and Discoveries; . . . .

35 U.S.C. § 102(g) (in relevant part)

> Conditions for patentability; novelty and loss of right to patent
>
> A person shall be entitled to a patent unless--
>
> . . . .
>
> (g)(2) before such person's invention thereof, the invention was made in this country by another inventor who had not abandoned, suppressed, or concealed it.

35 U.S.C. § 135(a) (in relevant part)

> Interferences
>
> (a) Whenever an application is made for a patent which, in the opinion of the Director, would interfere with any pending application, or with any unexpired patent, an interference may be declared and the Director shall give notice of such declaration to the applicants, or applicant and patentee, as the case may be.

37 C.F.R. § 1.601(n) (in relevant part)

> Scope of Rules, Definitions
>
> (n) Invention "A" is the same patentable invention as an invention "B" when invention "A" is the same as (35 U.S.C. 102) or is obvious (35 U.S.C. 103) in view of invention "B" assuming invention "B" is prior art with respect to invention "A".

STATEMENT OF THE CASE

The controversy between Eli Lilly & Co. ("Lilly") and the University of Washington ("UW") concerns which party first invented a genetic sequence encoding a protein to treat severe sepsis and, therefore, whether the patent claims to it are valid. The U.S. Patent and Trademark Office ("PTO") refused to determine the first inventor and the Federal Circuit affirmed its decision.

1. Lilly and UW Claim Genetic Sequences that Encode a Lifesaving Drug to Treat Severe Sepsis

The subject matter of this dispute is the invention underlying the Lilly drug Xigris®, which was developed by Lilly and hailed by the Food and Drug Administration as "the first biologic treatment for the most serious forms of sepsis, a life-threatening illness caused by severe infection." *See* FDA Press Release, November 21, 2001, available at http://www.fda.gov/bbs/topics/NEWS/2001/NEW00780.html. This life-saving drug is a protein called human activated Protein C (APC), which is produced from the genetic code claimed in Lilly's application. *See id.*

APC is administered to a patient as a purified protein. Production of large quantities of this purified protein is possible because Lilly discovered its genetic sequence, or "cDNA" sequence, which determines the chemical makeup of the APC protein. The cDNA sequence of human Protein C is the subject matter of the claims of Lilly's patent application and UW's patent. The exact sequences that each party identified, though, differ slightly at two of the different subunits that make up the cDNA chain, although they produce the same protein.

In addition to the specific species of cDNA sequences claimed by Lilly and UW, UW also included claim 1, which includes a group, or "genus", of cDNA sequences that can be construed as including *every* cDNA sequence that produces APC. After learning of UW's potentially broad patent claim, Lilly provoked an interference proceeding in which the first inventor, and therefore the party entitled to a patent claiming the common subject matter, would be determined by the PTO. *See* 37 C.F.R. § 1.601, *et seq.*

Had UW invented its sequence first, and Lilly's invention came later, the two inventions could be distinct, and separate patents for each could be entirely valid. This case arises because, presumptively at least, exactly the opposite is true: Lilly's presumptively prior invention makes the UW patent just a second patent claiming the same thing that Lilly already discovered, albeit claimed in the UW patent more generically.

After Lilly requested an interference, one was declared by the PTO Board of Patent Appeals and Interferences ("the Board").

2. The Interference

The Board found Lilly to be the "senior party," due to its earlier filing date, and UW the "junior party." *See* 37 C.F.R. § 1.601(m) ("A *senior party* is the party with the earliest effective filing date as to all counts . . . . A *junior party* is any other party."). As the junior party, UW had the burden of proving an earlier date of invention than the date that Lilly would assert during the proceedings. 37 C.F.R. § 1.657(a) ("A rebuttable presumption shall exist that, as to

each count, the inventors made their invention in the chronological order of their effective filing dates. The burden of proof shall be upon a party who contends otherwise.").

As required in interference practice, the PTO also determined which of the parties' claims would be considered in the priority determination. Only UW's "species" claim was considered, while all of Lilly's claims were considered. The failure to include UW's "genus" claim occurred even though Lilly's requests for interference alerted the PTO Examiner to the possibility of common subject matter in all of UW's claims and the Examiner appeared to agree. Nevertheless, the Board did not choose to consider UW's genus claim, even though it has a potentially broad scope that could include Lilly's claimed sequence.

During a threshold motion period, UW filed a motion for judgment based on "no interference-in-fact" as defined in 37 C.F.R. § 1.601(j). UW's motion asserted that the two species of cDNA sequences claimed by UW and by Lilly were patentably distinct. Lilly also filed a motion to have UW's genus claim included in the interference so that all of UW's claimed subject matter would be considered for a priority determination.

After a hearing, the Board determined that there was no interference-in-fact between UW's and Lilly's species claims. Lilly does not dispute these findings because the specific genetic sequences recited in Lilly's and UW's species claims are not the same and do not interfere.

Lilly does dispute the PTO's decision that UW's generic claim did not interfere with any of Lilly's claims. While a genus often does not anticipate a species under

patent law principles, a species *does* anticipate a later invented genus. *See In re Slayter*, 276 F.2d 408 (C.C.P.A. 1960); *see also Titanium Metals Corp. of Am. v. Banner*, 778 F.2d 775, 781 (Fed. Cir. 1985).

The Board apparently used a "two-way test" to come to its decision. The "two-way test" is an interpretation of a rule defining "same patentable invention" in 37 C.F.R. § 1.601(n), which provides:

> Invention "A" is the same patentable invention as an invention "B" when invention "A" is the same as (35 U.S.C. 102) or is obvious (35 U.S.C. 103) in view of invention "B" assuming invention "B" is prior art with respect to invention "A". . . .

A "two-way test" requires that invention B must anticipate or render invention A obvious *and* invention A must anticipate or render invention B obvious before an interference will be conducted. In contrast, under a "one-way test," if one party's claim anticipates or renders obvious a claim of another party an interference is held. A second inquiry is not necessary once the first has been met.

Use of the "one-way" or "two-way test" is important in cases like the instant one where genus and species claims are presented by the parties. Interferences between these types of claims are not declared under the "two-way test," even though claims to a later-filed genus, which could be anticipated under 35 U.S.C. § 102 (g) by the earlier-filed species, will be allowed in the absence of a determination of whether the genus or the species was invented first. Under the "one-way test", interferences between these types of claims will be held because, even though the genus claim does not anticipate the species, the species anticipates the

genus. Therefore, the criteria defined in 37 C.F.R. § 1.601(n) is met, and the interference proceeds.

Without an interference, the priority of the genus claim, and therefore its validity in light of the species claim, cannot be known. This uncertainty is magnified when, as in the instant case, the genus claim is presented by the junior party. In this case, there is a presumption, under 37 C.F.R. § 1.657(a), that the genus claim is invalid due to anticipation by the earlier invented species claim.

Despite this conflict, the Board chose to rely on a strict "two-way test," and concluded that there is no interference-in-fact between Lilly's presumptively earlier invented species and UW's presumptively later-invented genus. Therefore, it terminated the interference.

3. The Appeal

Lilly appealed the Board's decision to the Federal Circuit. In an opinion authored by Judge Gajarsa, two members of the panel affirmed, though Judge Lourie wrote a dissenting opinion. The Federal Circuit based its decision almost entirely on deference to the PTO, under 35 U.S.C. § 135(a), which provides in relevant part:

> Whenever an application is made for a patent which, in the opinion of the Director, would interfere with any pending application, . . . an interference *may* be declared . . . .

(emphasis added). The majority interpreted this statute to mean that the PTO has complete, unrestrained discretion to interpret its rules as it chooses. App. 7-9. Specifically, the

majority found that the PTO's recent interpretation of 37 C.F.R. § 1.601(n) as being a "two-way test" was permissible.

At the same time, the majority was fully aware of the evils of a rigid "two-way test." It found that:

> This court's case law suggests that the two-way test is underinclusive because it concludes there is no interference-in-fact even if an interference proceeding would have led to the conclusion that the species was invented before the genus. On the other hand, the one-way test is overinclusive because it concludes there is an interference-in-fact even if an interference proceeding would have led to the conclusion that the genus was invented before, and separately patentable from, the species.

App. 14. The majority affirmed the PTO's choice of the underinclusive evil. The effect of this evil on the first inventor's rights and the Patent Statute were not addressed.

The Federal Circuit's decision was only a 2-1 majority opinion. Judge Lourie wrote a dissent, concluding that an interference should be held under these facts. Although Judge Lourie agreed that the PTO has discretion to declare an interference, he found "that discretion is not unlimited. It is cabined by the requirement that it not be exercised contrary to the statute under which the Director operates the PTO . . . ." App. 19. Furthermore, Judge Lourie found the PTO's use of a "two-way test" to implement 37 C.F.R. § 1.601(n) to be an abuse of discretion because the Rule describes a "one-way test" on its face. App. 20-21.

After construing UW claim 1 as a genus, App. 22, Judge Lourie applied the "one-way test" and found that this

claim is the same patentable invention as Lilly's claims under the clear meaning of 37 C.F.R. § 1.601(n). *See id.*

Finally, Judge Lourie rejected the argument that the PTO should be able to alter the definition of "same patentable invention" to limit the number of interferences and thus conserve resources. He countered that determining priority

> is the job of the Office, which has the expertise to evaluate contending claims for patent, to determine which of those claims have priority and should issue as patents. It is clearly more efficient for even an overburdened Patent Office to make determinations in the arcane world of interferences than for the overburdened courts to do so.

App. 23. Despite Judge Lourie's clear understanding, his dissent was not enough to persuade the majority, which merely deferred to the PTO.

4. Petition for Rehearing

Lilly petitioned for panel rehearing and rehearing en banc. Although two other judges, Judge Newman and Judge Rader, would have reheard the case, the petition was denied. App. 67.

REASONS FOR GRANTING THE WRIT

Under the Federal Circuit's holding in this case, two patents will issue with claims to the same invention, without ascertaining the first inventor. Not only is this contrary to the intuitive concept that one invention is deserving of only one patent, the result is also contrary to the Patent Statute,

which prohibits issuance of a patent if "before such person's invention thereof, the invention was made in this country by another inventor who had not abandoned, suppressed, or concealed it." 35 U.S.C. § 102 (g)(2).

By ignoring this basic tenet of patent law, the majority has created a conflict with the precedent of its predecessor, *see Aelony v. Arni,* 547 F.2d 566, 570 (C.C.P.A. 1977) ("Sections 102, 103, and 135 of 35 USC clearly contemplate -- where different inventive entities are concerned -- that only one patent should issue for inventions which are either identical to or not patentably distinct from each other."), its own precedent, *see Apotex USA, Inc. v. Merck & Co.,* 254 F.3d 1031, 1035 (Fed. Cir. 2001) ("Section 102(g) operates to insure that a patent is awarded only to the 'first' inventor in law."), and even the PTO's precedent, *see Ex parte McGrew*, 41 U.S.P.Q.2d 2004, 2006 (Bd. Pat. App. & Int. 1995) ("For the PTO to knowingly burden the public with two patents to the same invention would violate the 'one patent for one invention' intention of the statute."), *aff'd*, 120 F.3d 1236 (Fed. Cir. 1997). In fact, the majority's holding has allowed two patents to issue to UW and Lilly, when it would not have allowed them to issue if they were assigned to one party. *See Eli Lilly and Co. v. Barr Labs., Inc.,* 251 F.3d 955 (Fed. Cir. 2001) and *Geneva Pharm. Inc. v. GlaxoSmithKline P.L.C.*, 349 F.3d 1373 (Fed. Cir., 2003).

When conflicting patents may result from the inventions of two different parties, a determination of priority of invention is necessary, as provided in 35 U.S.C. § 135(a), which states that "[t]he Board of Patent Appeals and Interference shall determine questions of priority of the inventions . . . ," once an interference has been declared. In this case, though, the PTO refused to continue the

interference because of a perceived drain on its resources, and the majority of the Federal Circuit deferred to it. The majority did not consider whether the PTO was due such total deference or the harms that issuing a presumptively invalid patent will do to the public, to those industries that rely on a strong patent system, and to Lilly. These harms are significant and outweigh any benefits to administrative efficiency that issuing two patents, where only one is deserved, can produce.

I. The Majority's Holding Has Allowed More Than One Patent to Issue for the Same Invention

When it refused to continue the interference, the PTO allowed both Lilly and UW to obtain patents with claims that can be construed to both encompass Lilly's specific cDNA sequence. Under the PTO's own interference rules, though, Lilly, as the first to file, is the presumptive first inventor of this genetic sequence in the absence of an interference. *See* 37 C.F.R. § 1.657(a). Therefore, Lilly's specific genetic sequence is presumptively anticipating prior art to UW's claim 1, construed as a genus claim. *See Slayter* and *Titanium Metals*. Thus, the refusal of patent interference has raised the UW patent from a patent, which, in the interference denied to Lilly, would have been presumptively invalid, into a patent that is now not only presumptively valid, but cannot be set aside absent clear and convincing evidence of invalidity. *See Juicy Whip, Inc. v. Orange Bang, Inc.*, 292 F.3d 728, 736 (Fed. Cir. 2002), *cert. denied*, 537 U.S. 1019 (2002).

Neither UW, the PTO, nor the majority of the Federal Circuit has ever explained how this result is consistent with the fundamental concept of "one patent for one invention."

According to the Federal Circuit's predecessor, this result goes against the design of the Patent Statute, which provides that "[w]hoever invents or discovers any new and useful . . . composition of matter, may obtain *a* patent . . . ." 35 U.S.C. § 101. *See Aelony*, 547 F.2d at 570.

Furthermore, no explanation has ever been given how UW's claim 1 is valid under 35 U.S.C. §102(g)(2), as the presumptive later invention of one of the specific genetic sequences it can be construed to claim. *See New Idea Farm Equip. Corp. v. Sperry Corp.*, 916 F.2d 1561, 1566-67 (Fed. Cir. 1990); *see also Ex parte Kroekel*, 230 U.S.P.Q. 191, 195 (Bd. Pat. App. & Int. 1985), *aff'd,* 803 F.2d 705 (Fed. Cir. 1986); *Apotex USA, Inc. v. Merck & Co.,* 254 F.3d 1031, 1035 (Fed. Cir. 2001), *cert. denied*, 534 U.S. 1172 (2002). Without an interference, the PTO cannot know that the patent it has awarded to UW is a valid one, particularly when it is *prima facie* invalid.

This Court has previously held that even when an agency has discretion under one part of a statute, it cannot use that discretion to undermine any other part of the statute. *See MCI Telecomm. Corp. v. American Tel. and Tel. Co.*, 512 U.S. 218, 229 (1994). Similarly, this Court has held that an agency's interpretation of a regulation is invalid when it conflicts with other statutory provisions. *See United States v. Larionoff,* 431 U.S. 864, 873 (1977) (holding that even though an interpretation was not plainly inconsistent with the language of the regulation, it must be consistent with Congress's intent in the statutory scheme). As the D.C. Circuit has stated, "[w]hen Congress gives an agency its marching orders, the agency must obey all of them, not merely some," *Public Citizen v. Nuclear Regulatory Comm'n,* 901 F.2d 147, 156 (D.C. Cir. 1990), but here the Federal Circuit has allowed the PTO to ignore the basic

concepts of 35 U.S.C. § 101 and § 102 that one patent shall be awarded for one invention in favor of the discretion allowed to the PTO under a different part of the organic statute.

II. The Majority's Holding that Allows Two Patents for One Invention Conflicts with Federal Circuit Precedent Regarding Multiple Patent Claims

This Court has warned the Federal Circuit that it "must be cautious before adapting changes that disrupt the settled expectations of the inventing community." *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 739 (2002); *see also Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 28 (1997), but the results of the current holding are in direct conflict with recent Federal Circuit jurisprudence on patent claims to common subject matter. In both *Barr* and *Geneva*, the court held that genus claims presented after species claims cannot exist with the full rights normally accorded to patentees when these claims are owned by one party, facts that are nearly identical to those of the instant case.

Specifically, in *Barr* and *Geneva*, the Federal Circuit considered the situation in which a party first presented narrow claims in an early patent application, and later, the same party presented broad claims supported by the disclosure of the earlier patent. *See Barr*, 251 F.3d at 971, and *Geneva,* 349 F.3d at 1383. In both cases, the court found that the earlier, narrow claim was a "species" of the subject matter of the later, broader claim, which was deemed a "genus." Under the rule that a later genus claim limitation is anticipated by, and therefore not patentably distinct from, an earlier species claim, *Barr,* 251 F.3d at 971, the court

found that in both cases the later genus claim was invalid, *Barr*, 251 F.3d at 972; *Geneva,* 349 F.3d at 1384.

In contrast, two different patents are now allowed to coexist with full patent rights, under essentially the same facts, except that the patents are owned by two different parties, Lilly and UW, rather than a single one. Like the later filed claims in *Barr* and *Geneva*, UW's later filed claim 1 can be construed to be a generic claim encompassing Lilly's earlier filed species claims. In fact, were Lilly or UW to license the other's patent, the facts in *Barr* and *Geneva* would exist. Lilly and UW would each have the benefit of an extended patent term, an outcome the Federal Circuit condemned for the owners of the patents in *Barr* and *Geneva*.

The Federal Circuit should have followed its own precedent to find, as Judge Gajarsa wrote, that "[a] patentable distinction does not lie where a later claim is anticipated by an earlier one," *Barr*, 251 F.3d at 970. Instead, the Federal Circuit affirmed the PTO's decision to avoid making a determination of whether UW's invention was actually made before Lilly's.

III. When Two Patents are Issued that Claim the Same Invention, the Public is Harmed, the Patent System is Harmed, and the Party with the Valid Patent Is Harmed

Issuance of two patents to the same invention will create havoc in the patent system. The public is harmed because of the extended patent term that is created, the patent system is harmed because patents that are *prima facie* invalid erode confidence in the rights conferred with a patent, and

the holder of the valid patent is harmed because it does not enjoy the full rights it is due.

A. The Public Is Harmed Because There Is an Extension of the Term of Exclusivity from the Claimed Subject Matter

Issuance of two patents for one invention creates an effective patent term extension, which is a burden to the public and is contrary to the Constitutional provision "to promote the Progress of Science and useful Arts, by securing for *limited* Times to Authors and Inventors exclusive Right to their respective Writings and Discoveries . . . ." U.S. Const., Art. I, § 8[8] (emphasis added).

After Lilly's patent has expired the public expects to be able to use Lilly's specific cDNA sequence, but it will still be excluded by UW's broad claim, even if UW is not entitled to it. Specifically, Lilly's patent will expire on October 4, 2005, while UW's patent will expire on November 6, 2007, two years and one month later. This extra-statutory period of exclusivity deprives the public of the chance to make, use, or sell Lilly's sequence, and subjects it to "harassment" of an infringement suit by UW for a period beyond which even Lilly can enforce its rights.

B. The Patent System As a Whole Is Harmed Because It Promotes Invalid Patents

By allowing two patents that claim the same invention to exist, the majority has injured the patent system. A recent report, *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy*, 2003 WL

22507757 (F.T.C. October, 2003), by the Federal Trade Commission ("FTC"), found that "[w]e should be wary of creating unwarranted market power by granting unwarranted patents," *id.* at *38 (Chap. 1, p. 37), such as those which presumptively do not meet the standards for patentability, *see id.* Although the FTC advised that "[w]ell-considered PTO guidelines can prevent invalid patents that capture basic ideas and research and thus thwart competition in emerging fields," *id.* at *33 (Chap. 1, p. 30), the majority endorsed a PTO policy that promotes invalid patents by refusing to determine who is entitled to the patent in a priority contest.

The problem of invalid patents is very widespread, with possibly 45-46% of all patents litigated held to be invalid. *See id.* at *127 (Chap 5., p.6). In fact, the FTC was so concerned with the quality of patents being issued by the PTO that it even recommended lowering the standard by which patent validity is challenged to only a "preponderance of the evidence," instead of the current requirement for "clear and convincing evidence" of invalidity. *Id.* at *139 (Chap. 5, pp. 26-28). But, the majority would allow even more presumptively invalid patents, such as UW's, and, thus, ignore a problem that led to this drastic recommendation.

In the biotechnology industry the problem of invalid patents is even more acute. As one commentator has observed, "there are these bad patents that sit out there and you can't touch them." *Id.* at *6 (Executive Summary, p. 6). Under the majority's holding these "bad patents" can arise under scenarios such as that explained by Guilford Pharmaceuticals in their *Amicus* Brief filed in support of the rehearing of this case. Specifically, an innovative drug company may develop a novel drug and file a patent application to claim it. Under the majority's holding, another company may later file its own patent application, not

reciting this particular drug, but claiming a genus encompassing the drug. Although the first company actually discovered the drug and is facing a long regulatory road costing millions of dollars before marketing it, the company might reap no reward and the public may receive no benefit because the second company's patent could be used to block it. Equally intolerable is the choice facing the innovator to pay a royalty extracted by the later applicant for a patent or to face the threat of patent litigation. The majority never addressed this harm when it bowed to the PTO's exercise of discretion to conserve resources by not holding an interference.

C. Lilly Is Harmed Because It Has Lost a Constitutional Property Right and Has No Effective Legal Recourse

Lilly is particularly hurt by the issuance of a patent to UW that claims the same invention. The majority's decision provided two rights of exclusivity to two parties, wherein Lilly, as the presumptive first inventor of an anticipating claim, is the only party deserving of this right, unless its priority is disproved. As the first inventor, it is only logical that Lilly should not be subject to suit by one who invented later, absent a specific statutory reason. *See Ex parte Rapse*, 156 U.S.P.Q. 217 (Bd. Pat. App. 1967) (Federico, concurring). The Federal Circuit's holding creates the anomalous situation that during the term of Lilly's patent, and even after it has expired, when Lilly has dedicated its invention for full and free use by the public, Lilly may still be excluded from its own invention by UW, despite the fact that UW has not been shown to deserve a broad patent claim.

Lilly's private interest in the property of its patent is significant. Lilly spent nearly a billion dollars and over 20

years developing Xigris®, yet it may have to obtain a license from UW to practice what Lilly presumptively invented first.

To address these harms, the PTO perfunctorily stated that if Lilly "[believes] that an actual controversy exists between the UW . . . patent and Lilly's activities, Lilly may file a declaratory judgment action in district court." App. 64. While, theoretically, Lilly could bring action in district court to assert priority of invention under 35 U.S.C. § 291 ("The owner of an interfering patent may have relief against the owner of another by civil action, and the court may adjudge the question of the validity of any of the interfering patents, in whole or in part."), *see Walker Process Equip., Inc. v. Food Mach. & Chem. Corp.*, 382 U.S. 172, 176 (1965), an interference in district court would likely be dismissed because the same "two-way test" would be used with the same result. Indeed, the Federal Circuit recently applied this standard when reviewing an interference proceeding in a district court under 35 U.S.C. § 291. *See Medichem, S.A. v. Rolabo, S.L.*, No. 02-1461, -1480, slip op. at 9-10 (Fed. Cir. Dec. 23, 2003).

Therefore, the PTO's advice for an alternate remedy by "[filing] a declaratory judgment action in district court" rings hollow. In fact, the only remedy available to Lilly is to infringe UW's patent, and then, after Lilly is sued by UW, assert a defense that UW's broad claim is invalid. Had the majority of the court considered this, though, it should have seen the error in a holding that promotes patent infringement as the only way to assert a property right. Instead, the majority should have heeded its own advice that "[t]he public interest in the benefits of a patent system is best met by procedures that resolve administratively questions affecting patent validity that arise before the PTO. To do otherwise is contrary to the PTO's mission to grant presumptively valid

patents, . . . and thus disserves the public interest." *Perkins v. Kwon,* 886 F.2d 325, 328-29 (Fed. Cir. 1989).

IV. The Majority Affirmed the Issuance of Two Patents for One Invention Because It Accorded the PTO with Deference Beyond What It Deserves

The Federal Circuit erred by providing the PTO with deference to impose a wooden "two-way test" beyond what it was due under principles of administrative law and under the Patent Statute. *Chevron U.S.A. Inc. v. Nat'l Res. Def. Council, Inc.*, 467 U.S. 837 (1984), provides agencies with deference in their statutory interpretations where Congress has been silent, and *Bowles v. Seminole Rock & Sand Co.*, 325 U.S. 410 (1945), provides deference for agency interpretations of their own rules. As an agency, *Dickinson v. Zurko*, 527 U.S. 150 (1999), the PTO's decisions also deserve some deference. In fact, Congress has provided the PTO with some discretion to declare an interference under 35 U.S.C. § 135(a), and this discretion has been upheld in cases where the facts differ from the instant case. For example, in *Ewing v. U.S. ex rel Fowler Car Co.*, 244 U.S. 1 (1917), this Court upheld the PTO's discretion to refuse to declare an interference when the later-filing party could not provide any evidence of prior invention, a practice the PTO has now codified in 37 C.F.R. § 1.608.

But, the Federal Circuit has not always approved of the PTO's exercise of its discretion in refusing to declare an interference. For instance, in *Barton v. Adang*, 162 F.3d 1140, 1144 (Fed. Cir. 1998), while the court recognized that 35 U.S.C. § 135(a) uses the permissive term "may" when referring to the Director's discretion to declare an interference, it also remanded the PTO's dismissal of an

interference because it found good cause for conducting one. *See Barton*, 162 F.3d at 1146. As in *Barton*, the Federal Circuit should have been more vigilant about the facts of this particular case and the harm that has resulted by issuing two patents claiming the same invention.

A. The PTO Exercised Its Discretion Only to Conserve Resources, Not to Further the Goals of the Patent System

In the context of announcing the use of the "two-way test" for declaring an interference, the PTO explained that: "Any decision to expand the nature of interference proceedings will have a resource consequence for USPTO and for applicants and patentees involved in interferences." 65 Fed. Reg. 79,809, 79,810 (2000). In an *Amicus* brief in the appeal of this case, the PTO justified the use of the "two-way test" because under the previous standard "a significant number of additional interferences will occur . . . ." PTO *Amicus* Brief, February 4, 2003, at 9. It is clear then, that the PTO used its discretion in this case to reduce the number of interference proceedings and thus conserve its resources. No other rationale for the "two-way test" has ever been provided, either during this case or in Federal Register notices.

Efficiency is not a sufficient reason, though, for issuing two patents for the same invention because "[r]egardless of how serious the problem an administrative agency seeks to address, however, it may not exercise its authority in a manner that is inconsistent with the administrative structure that Congress enacted into law." *See Ragsdale v. Wolverine World Wide, Inc.*, 535 U.S. 81 (2002) (quotations omitted). While it could be true that even after an interference both Lilly and UW may be entitled to patents,

it defies logic that the validity of a patent that negatively impacts another party's rights should *not* be determined, merely because the other patent *might* be valid and the PTO wants to save money.

The majority did not consider the PTO's justification in a broader context, as Judge Lourie did in his dissent when he observed that "'[i]t is clearly more efficient for even an overburdened Patent Office to make determinations in the arcane world of interferences than for the overburdened courts to do so." App. 23. Although Judge Gajarsa did not agree when he authored the instant opinion, he seems to now agree with Judge Lourie that the PTO is the best forum to determine questions of priority, because he recently wrote:

> The record generated by the Board, particularly in light of the Board's expertise in the matter, may permit a district court to avoid a needless duplication of efforts. Furthermore, a priority determination that results in the cancellation of the interfering claims of the . . . patent would eliminate the need for further proceedings in the district court altogether.

Medichem, slip op. at 13 The Federal Circuit's conflicting opinions on which forum is the best to decide questions of priority undermines the complete deference it accorded the PTO in the instant case. Here, the PTO exercised its discretion merely to make a questionable savings of resources, not to promote valid patents, as even Judge Gajarsa now understands.

B. The PTO Deserves Less Deference in this Case Because the "Two-Way Test" Is Not Longstanding

The majority characterized the PTO's use of a wooden "two-way test" as a "long-standing" interpretation of a rule. App. 14. But this interpretation is not long-standing. The "two-way test" was announced in a published decision of the PTO Board of Patent Appeals and Interferences in 1999, s*ee Winter v. Fujita*, 53 U.S.P.Q.2d 1234, 1243 (Bd. Pat. App. & Int. 1999) ("Resolution of an interference-in-fact issue involves a two-way patentability analysis."). Following this supposed restatement of "long-standing" policy, the PTO requested comments from the public on this policy. *See* 65 Fed. Reg. 79,809 (Dec. 20, 2000). It seems curious that a "long-standing" policy would suddenly need such attention. In fact, there were several comments from the public that noted the harm a "two-way test" would create. *See* Comment of the American Intellectual Property Law Association, available at http://www.uspto.gov/web/offices/dcom/bpai/rule/aipla.htm, Comment of the Intellectual Property Owners' Association, available at http://www.uspto.gov/web/offices/dcom/bpai/rule/ipo.htm, and Comment of Genentech, Inc. available at http://www.uspto.gov/web/offices/dcom/bpai/rule/sjohnston.htm.

Furthermore, the PTO has recently published a notice of a change in the language of the Rule to articulate a "two-way test." *See* 68 Fed. Reg. 66,648 (Nov. 26, 2003). In the proposed new Rule, "[a]n interference exists if the subject matter of a claim of one party would, if prior art, have anticipated or rendered obvious the subject matter of a claim of the opposing party *and vice versa*." *id.* at 66,689

(emphasis added). The term "and vice versa" has been added to the comparable definition in the current Rules. *See* 37 C.F.R. § 1.601(n). While the proposed Rule appears to be reflexive because of the term "and vice versa", its absence in the current Rule indicates that there is not a reflexive standard for interference under the PTO's existing Rules. The PTO applied the reflexive standard in this case, though.

Judge Lourie recognized this in his dissent when he explained that the current Rule "provides a one-way test, not a two-way test, as the Board erroneously held." App. 21. (Lourie, J., dissenting). The majority agreed that this understanding was a "plausible alternative reading" of the Rule. App. 14. That the PTO has now provided notice and asked for comments as a prelude to enacting a new Rule to change the current one to be reflexive, is a confirmation of Judge Lourie's interpretation and a tacit admission by the PTO that this was not the original standard it enacted for declaring an interference. *See* 49 Fed. Reg. 48,416, *et seq.* (Dec. 12, 1984).

In fact, the PTO has held interferences that did not meet a reflexive standard. For example, Interference No. 103,464, declared in September, 1996, and Interference 103,904 declared in August, 1994, involved biotechnology inventions that were claimed narrowly by one party and broadly by the other. Despite the differing scope, the PTO was willing to determine which party was entitled to a patent. Furthermore, the PTO has published opinions of priority determinations with facts similar to those of this case, wherein the senior inventor's claims rendered the junior inventor's claims unpatentable. *See Daniels v. Daum*, 214 U.S.P.Q. 911 (Bd. Pat. Int. 1982), *Antos v. Juguin,* 220 U.S.P.Q. 722 (Bd. Pat. Int. 1981), and *Sakano v. Rutemiller,* 158 U.S.P.Q. 47 (Bd. Pat. Int. 1968). It is clear from this

evidence and the PTO's curious behavior in reformulating the Rule regarding the standard for declaring interferences that, despite the Federal Circuit's characterization, that standard is not "long-standing."

Although "[t]his Court has rejected the argument that an agency's interpretation 'is not entitled to deference because it represents a sharp break with prior interpretations' of the statute in question," *Rust v. Sullivan*, 500 U.S. 173, 186 (1991), "an agency interpretation of a relevant provision which conflicts with the agency's earlier interpretation is entitled to considerably less deference than a consistently held agency view," *Good Samaritan Hosp. v. Shalala*, 508 U.S. 402, 417 (1993) (quotations omitted). There is no evidence that the "sharp break" in the "one-way test" the PTO previously used to hold interferences was ever considered by the Federal Circuit in this case. Instead, the court based its decision entirely on its deference to the PTO, even though the PTO is only trying to reduce the number of interferences to conserve resources and not to issue stronger, valid patents.

CONCLUSION

The Federal Circuit seems to be a willing partner to the PTO's pursuit of reducing costs, even if the fundamental concept of one patent for one invention has been compromised. Both the Federal Circuit and the PTO are willing to issue broad, undeserved claims and to extend patent terms, thus keeping inventions from the public domain, for the sake of sustaining a standard that allows the PTO to conduct fewer interference proceedings. The Court should act to halt this practice by bringing the PTO back to the guidelines the Constitution and Congress created for it. The Court should also intervene where the Federal Circuit's

reasoning is so internally inconsistent and conflicted that it does not provide clear direction for issuing and sustaining multiple patents on similar inventions.

Respectfully submitted,

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APPENDIX

APPENDIX A

United States Court of Appeals for the Federal Circuit

02-1610
(Interference No. 104,733)

ELI LILLY & CO.,

Appellant,

v.

BOARD OF REGENTS OF THE UNIVERSITY OF WASHINGTON,

Appellee.

Charles E. Lipsey, Finnegan, Henderson, Farabow, Garrett & Dunner, L.L.P., of Washington, DC, argued for appellant. With him on the brief were Kenneth J. Meyers and Deborah Katz. Of counsel on the brief were Brian P. Barrett and Steven P. Caltrider, Eli Lilly and Company, of Indianapolis, Indiana.

William F. Lee, Hale and Dorr LLP, of Boston, Massachusetts, argued for appellee. With him on the brief were Lisa J. Pirozzolo, of Boston, Massachusetts; and James L. Quarles III and Henry N. Wixon, of Washington, DC. Of counsel were Maria L. Maebius and William G. McElwain, of Washington, DC.

John M. Whealan, Solicitor, United States Patent and Trademark Office, of Arlington, Virginia, for amicus United States Patent and Trademark Office. With him on the brief were James A. Toupin, General Counsel; and Stephen Walsh and Henry G. Sawtelle, Associate Solicitors.

Appealed from: United States Patent and Trademark Office
Board of Patent Appeals and Interferences

United States Court of Appeals for the Federal Circuit

02-1610
(Interference No. 104,733)

ELI LILLY & CO.,

Appellant,

v.

BOARD OF REGENTS OF THE UNIVERSITY OF WASHINGTON,

Appellee.

DECIDED: July 3, 2003

Before MICHEL, LOURIE, and GAJARSA, Circuit Judges.
Opinion for the court filed by Circuit Judge GAJARSA.
Circuit Judge LOURIE dissents.
GAJARSA, Circuit Judge.

This is an appeal from a patent interference proceeding before the United States Patent and Trademark Office ("PTO") Board of Patent Appeals and Interferences ("Board"). The Board granted the Board of Regents of the University of Washington's ("UW's") motion declaring that no interference-in-fact existed on the grounds that the invention of the corresponding claims of U.S. Reissue

Application No. 09/185,663 ("the '663 reissue application") to Eli Lilly & Co. ("Lilly") are separately patentable over that of U.S. Patent No. 5,302,529 ("the '529 patent") assigned to UW. Bd. of Regents of the Univ. of Wash. v. Eli Lilly & Co., Patent Interference No. 104,733 (Bd. Pat. App. & Int. June 11, 2002). Because the Director of the PTO's ("Director's") interpretation of 37 C.F.R. § 1.601(n) as establishing a "two-way" test for determining whether two parties are claiming the "same patentable invention" is neither plainly erroneous nor inconsistent with the regulation, and the Board committed no reversible error in applying the two-way test to determine that the '529 patent and the corresponding claims of the '663 reissue application do not define the same patentable invention, we affirm.

I. BACKGROUND

On November 4, 1998, Lilly filed the '663 reissue application to surrender its own U.S. Patent No. 4,775,624 ("the '624 patent") and requested an interference between its reissue application and the '529 patent. The Board declared an interference on August 7, 2001 between the '663 reissue application and the '529 patent. The claimed subject matter relates to a complementary deoxyribonucleic acid ("cDNA") sequence that codes for human protein C, which plays an important role in the regulation of blood coagulation and generation of fibrinolytic activity in vivo. Lilly filed new claims 1-82 and 84-90 of the '663 reissue application and requested that only claim 3 of the '529 patent be designated as corresponding to the sole count in the interference: "A plasmid or transfer vector of Foster claim 3 [of the '529 patent]."

Claim 1 of the '529 patent, which is the independent claim from which claim 3 depends, reads:

> 1. A bacterial plasmid or bacteriophage transfer vector comprising cDNA coding for the amino acid sequence of FIG. 3, starting with alanine, number 1, and ending with proline, number 419, said cDNA sequence coding for human protein C.

'529 patent, col. 6, ll. 48-52.

> Claim 3 recites:
> 3. The plasmid or transfer vector of claim 1, comprising the cDNA sequence of FIG. 3, from bp [base pair] 127 to bp 1383.

Id. at col. 6, ll. 57-59.

UW's '529 patent was a continuation of, and was accorded the benefit of, U.S. Patent No. 4,968,626 (issued Nov. 6, 1990), which was filed on August 15, 1985. Lilly's '663 reissue application was accorded the benefit of the February 8, 1985 filing date of the '624 patent (issued Oct. 4, 1988). Accordingly, in the declaration of interference in which claim 3 of the '529 patent was the interference count, Lilly was made the presumptive senior party.

During the preliminary motions period, UW filed a motion for judgment on the ground that there is no interference-in-fact, explaining that the parties' cDNA molecules have different sequences, i.e., chemical structures. The Board agreed that the evidence established the differences and found that Lilly's claims do not define the same patentable invention as claim 3 of the '529 patent. Thus, the Board granted UW's motion for no interference-in-fact and dismissed the interference.

After failing to instigate an interference with the '529 patent based upon claim 3, Lilly filed a motion to redefine the interfering subject matter by designating claim 1 of the '529 patent as also corresponding to the sole count in the interference. Lilly proposed two alternative constructions of claim 1 of the '529 patent: (1) a narrow construction claiming the specific cDNA sequence recited in Figure 3 of the '529 patent ("species claim construction"), and (2) a broad construction claiming any cDNA sequence that codes for human protein C ("genus claim construction"). Applying a two-way test pursuant to its regulation, 37 C.F.R. § 1.601(n), the Board found that, whether claim 1 of the '529 patent is construed as a genus or as a species, the corresponding claims of the '663 reissue application do not define the "same patentable invention" as claim 1 of the '529 patent, and determined that there is no interference-in-fact between the corresponding claims of the '663 reissue application and claim 1 of the '529 patent. Accordingly, the Board dismissed as moot Lilly's motion to redefine the interfering subject matter by designating claim 1 of the '529 patent as also corresponding to the count. Lilly timely appealed to this court, and we have jurisdiction pursuant to 28 U.S.C. § 1295(a)(4)(A).

II. STANDARD OF REVIEW

An agency's interpretation of its own regulations is entitled to substantial deference, and that interpretation will be accepted unless it is plainly erroneous or inconsistent with the regulation. Auer v. Robbins, 519 U.S. 452, 461-62 (1997) (citing Bowles v. Seminole Rock & Sand Co., 325 U.S. 410, 414 (1945)); Am. Express Co. v. United States, 262 F.3d 1376, 1382 (Fed. Cir. 1996).

This court reviews a Board decision pursuant to the permissive rules governing a patent interference proceeding for abuse of discretion. Abrutyn v. Giovanniello, 15 F.3d 1048, 1050-51 (Fed. Cir. 1994) (citing Gerritsen v. Shirai, 979 F.2d 1524, 1527-28 (Fed. Cir. 1992)). An abuse of discretion occurs if the decision (1) is clearly unreasonable, arbitrary, or fanciful; (2) is based on an erroneous conclusion of law; (3) rests on clearly erroneous fact findings; or (4) involves a record that contains no evidence on which the Board could rationally base its decision. Id. This court reviews the legal conclusion of obviousness without deference. In re Gartside, 203 F.3d 1305, 1316 (Fed. Cir. 2000). Anticipation is a question of fact, and this court upholds the decisions of the Board on factual matters if there is substantial evidence in the record to support the Board's findings. In re Hyatt, 211 F.3d 1367, 1371-72 (Fed. Cir. 2000).

III. DISCUSSION

A. 35 U.S.C. § 135(a)

This case presents the question of whether the Director's two-way test for determining whether two parties claim the "same patentable invention" reflects a permissible reading of 37 C.F.R. § 1.601(n), promulgated pursuant to 35 U.S.C. § 135(a), where a species claim to a presumptive senior party allegedly anticipates a genus claim to a presumptive junior party. We also consider whether the Board reasonably has applied the two-way test to dismiss as moot a motion to redefine the interfering subject matter by designating a claim as corresponding to a count.

Pursuant to authority granted by 35 U.S.C. § 135, the Director established the current interference rules to

implement the Patent Law Amendments Act of 1984, Pub. L. No. 98-622, §§ 201-02. Patent Interference Proceedings, 49 Fed. Reg. 48,416 (Dec. 12, 1984); 37 C.F.R. § 1.601-1.690 (2003). Section 135 of the United States Code, Title 35, governs patent interference proceedings, which are designed to determine whether two patent applications (or a patent application and an issued patent) are drawn to the "same patentable invention" and, if so, which of the competing parties was first to invent the duplicative subject matter. See Conservolite, Inc. v. Widmayer, 21 F.3d 1098, 1100-01 (Fed. Cir. 1994). The statutory basis for declaring an interference proceeding, 35 U.S.C. § 135(a), reads in pertinent part:

> Whenever an application is made for a patent which, in the opinion of the Director, would interfere with any pending application, or with any unexpired patent, an interference may be declared . . . . The Board of Patent Appeals and Interferences shall determine questions of priority of the inventions and may determine questions of patentability.

35 U.S.C. § 135(a) (2000) (emphases added). The plain meaning of this statute demonstrates that Congress has expressly indicated its preference that the declaration of an interference pursuant to § 135 be discretionary. Barton v. Adang, 162 F.3d 1140, 1144 (Fed. Cir. 1998) ("The plain meaning of this statute is clear from the use of the permissive term 'may' that the [Director] has discretion whether to declare an interference."); see also In re Alappat, 33 F.3d 1526, 1531 (Fed. Cir. 1994) (en banc) ("When statutory interpretation is at issue, the plain and unambiguous meaning of a statute prevails in the absence of clearly expressed legislative intent to the contrary."). Section 135(a) states that

the Board shall determine questions of priority once an interference proceeding is declared. This authority for the Board to determine questions of priority, however, does not vitiate the Director's discretion to begin or discontinue an interference once declared. See 35 U.S.C. § 135(a). Accordingly, the mandatory language only instructs the Board of its jurisdiction over an active interference. See id.

B. 37 C.F.R. § 1.601(n)

Lilly concedes that 35 U.S.C. § 135(a) permits some discretion, and Lilly also does not raise any general challenge to the Director's reliance on the two-way test to determine whether two parties are claiming the "same patentable invention." Lilly, however, argues that the Director's discretion under 35 U.S.C. § 135(a) is bridled by statutory mandate that requires issuance of only one patent to the first inventor. See 35 U.S.C. § 102(g) (2000). Specifically, where a genus claim to a presumptive junior party is allegedly anticipated by a species claim to a presumptive senior party, Lilly argues that the proper test for whether two claims are the same patentable invention is a "one-way" test, i.e., the claimed invention of Party A is the same patentable invention as the claimed invention of Party B when the claimed invention of Party A anticipates or renders obvious the claimed invention of Party B, or the claimed invention of Party B anticipates or renders obvious the claimed invention of Party A.

We conclude that the Board properly rejected Lilly's arguments. Under regulations promulgated by the Director, an interference proceeding is declared when two parties are claiming the "same patentable invention." 37 C.F.R. § 1.601(i). According to the regulations, an "interference-in-

fact" exists only if both parties to an interference have at least one claim that defines the "same patentable invention." Id. § 1.601(j). The phrase "same patentable invention" is defined as follows:

> Invention "A" is the same patentable invention as an invention "B" when invention "A" is the same as (35 U.S.C. [§] 102) or is obvious (35 U.S.C. [§] 103) in view of invention "B" assuming invention "B" is prior art with respect to invention "A." Invention "A" is a separate patentable invention with respect to invention "B" when invention "A" is new (35 U.S.C. [§] 102) and non-obvious (35 U.S.C. [§] 103) in view of invention "B" assuming invention "B" is prior art with respect to invention "A."

Id. § 1.601(n). The first sentence of § 1.601(n) states that "same patentable invention" means that the invention of one party anticipates or renders obvious the other party's invention. Section 1.601(n) also defines "separate patentable invention" to mean that the invention of one party is new and nonobvious in view of the other party's invention.

The Director, in an amicus brief, interprets § 1.601(n) as requiring a two-way test to determine whether two parties claim the "same patentable invention." The two-way test assures that an interference proceeding will be conducted only when warranted. The Director's approach rejects a wooden requirement under the overinclusive one-way test of declaring an interference proceeding where a species claim allegedly anticipates a genus claim. If the interference proceeding, however, leads to a conclusion that the genus claim was invented first, it is possible that both the genus and the species are separate patentable inventions. Thus, the

Director's two-way test avoids the proliferation of unnecessary, wasteful interference proceedings concluding that both parties are entitled to patents in situations in which the claimed inventions do not define the same patentable invention, but merely overlap in scope. This is the clear application of discretion that is inherent in the authority granted pursuant to 35 U.S.C. § 135(a) of the statute.

Because the two-way test is an interpretation of the Director's own regulations, the Director's interpretation of them is controlling unless "plainly erroneous or inconsistent with the regulation." Auer, 519 U.S. at 461 (citing Seminole, 325 U.S. at 414); see also United States v. Cleveland Indians Baseball Co., 532 U.S. 200, 220 (2001) (giving "substantial judicial deference" to the Internal Revenue Service's reasonable longstanding interpretation of its own regulations); Thomas Jefferson Univ. v. Shalala, 512 U.S. 504, 512 (1994) (noting that the agency's interpretation must be given "controlling weight unless it is 'plainly erroneous or inconsistent with the regulation'" (quoting Seminole, 325 U.S. at 414)); Udall v. Tallman, 380 U.S. 1, 16 (1964) (stating that when "an interpretation of an administrative regulation [is required,] a court must necessarily look to the administrative construction of the regulation if the meaning of the words used is in doubt" (citing Seminole, 325 U.S. at 413-14)); see generally Richard J. Pierce, Jr., Administrative Law Treatise § 6.11 (4th ed. 2002). We have formulated the degree of this deference, under our jurisprudence, variously as "substantial," Am. Express, 262 F.3d at 1382-83, and, in the context of a ruling of the Board, as "considerable respect," Kubota v. Shibuya, 999 F.2d 517, 520 (Fed. Cir. 1993) (citing Ford Motor Credit Co. v. Milhollin, 444 U.S. 555, 566 (1980)). See also Bayer AG v. Carlsbad Tech., Inc., 298 F.3d 1377, 1381 (Fed. Cir. 2002); Morganroth v. Quigg, 885 F.2d 843, 848 (Fed. Cir.

1989) (stating that the Director's "interpretation of [the regulatory provisions governing abandonment and revival of patent applications] is entitled to considerable deference."). But see Dethmers Mfg. Co. v. Automatic Equip. Mfg. Co., 272 F.3d 1365, 1370 (Fed. Cir. 2001) (subjecting the PTO's interpretation of its own reissue rule to a de novo standard of review), petition for cert. filed, 71 U.S.L.W. 3191 (U.S. Sep. 11, 2002) (No. 02-429).

The deferential standard of Seminole is easily met here.[1] The critical phrase "assuming invention B is the prior art with respect to invention A" comfortably bears the meaning the Director assigns. Because it is not conclusively known which of the two inventions is the prior art and the critical phrase does not require that invention B is the invention of the presumptive senior party, the Director may interpret the phrase to mean that both UW and Lilly may be the assumed "prior art" invention B. Thus, the claimed invention of Party B (UW) is assumed to be prior art vis-à-vis Party A (Lilly) and the claimed invention of Party B (Lilly) is assumed to be prior art vis-à-vis Party A (UW). Thus, under the Director's chosen two-way test, to determine whether two parties are claiming the "same patentable invention," the claimed invention of Party B (UW) must

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1 To reach Seminole deference, a court must first address the straightforward Chevron question, if presented, of whether a procedural regulation promulgated by the PTO violates the statute. Merck & Co. v. Kessler, 80 F.3d 1543, 1549 (Fed. Cir. 1996) (stating that 35 U.S.C. § 6(a) authorizes the Director to promulgate procedural but not substantive regulations); see also Chevron U.S.A. Inc. v. Natural Res. Def. Council, Inc., 467 U.S. 837, 842-43 (1984). Because Lilly does not dispute the validity of the regulation, we only address the Seminole question of whether the agency's interpretation is consistent with the regulation.

anticipate or render obvious the claimed invention of Party A (Lilly) and the claimed invention of Party B (Lilly) must anticipate or render obvious the claimed invention of Party A (UW). In the circumstances of this case, where the agency's interpretation of its own regulation is at least as plausible as competing ones, there is little, if any, reason not to defer to the agency's construction.

Besides being textually defensible, the Director's reading of 37 C.F.R. § 1.601(n) comports with the PTO's Notice of Final Rule that accompanied the promulgation of the regulation. 49 Fed. Reg. at 48,433. According to the Notice of Final Rule, the PTO addressed the issue of genus and species claims by stating that genus and species claims define "separate patentable inventions" if the species is "separately patentable from the genus." Id. at 48,433 ("[T]he standard of patentability will not be applied 'on a mutual basis.' Thus, if a species is patentable over a genus, the species is a 'separate patentable' invention from the genus.").

Furthermore, the two-way test for determining whether two parties claim the "same patentable invention" is reasonable and consistent in light of the precedent concerning genus/species inventions. On the one hand, this court has explained, "case law firmly establishes that a later genus claim limitation is anticipated by, and therefore not patentably distinct from, an earlier species claim." Eli Lilly & Co. v. Barr Labs., Inc., 251 F.3d 955, 971 (Fed. Cir. 2001), cert. denied, 122 S. Ct. 913 (2002). On the other hand, earlier disclosure of a genus does not necessarily prevent patenting a species member of the genus. See, e.g., Bristol-Myers Squibb Co. v. Ben Venue Labs, Inc., 246 F.3d 1368, 1380 (Fed. Cir. 2001).

A primary issue unleashed by application of the two-way test has been whether, under that test, an "interference-in-fact" should exist whenever there exists a theoretical possibility of an interference, or rather only when the parties' claims define the "same patentable invention." This court's case law suggests that the two-way test is underinclusive because it concludes there is no interference-in-fact even if an interference proceeding would have led to the conclusion that the species was invented before the genus. On the other hand, the one-way test is overinclusive because it concludes there is an interference-in-fact even if an interference proceeding would have led to the conclusion that the genus was invented before, and separately patentable from, the species. Section 1.601(n) reasonably can be interpreted to require an election between either a one-way or a two-way test. The Director has reasonably opted for a two-way test to avoid subjecting broad patents for basic inventions to interferences, some of which would have been unnecessary. To read the regulation, as Lilly and our colleague in dissent urge, to require the continuance of an interference proceeding where a genus claim to a presumptive junior party is allegedly anticipated by a species claim to a presumptive senior party, is a plausible alternative reading, but a reading which in the Director's discretion he has chosen not to accept.

While Lilly's objections would perhaps support an alternative one-way test where a species claim to a presumptive senior party allegedly anticipates a genus claim to a presumptive junior party, we cannot conclude that they compel it. The Director's view that a presumptive senior party with a species claim and a presumptive junior party with a genus claim are not so differently situated with regard to determining a separate patentable invention as to require revision of the Director's long-standing two-way test simply

cannot be said to be unreasonable. Accordingly, we hold that the Director's interpretation of 37 C.F.R. § 1.601(n) as establishing a two-way test for determining whether two parties are claiming the "same patentable invention" is neither plainly erroneous nor inconsistent with the language of the regulation.

C. Motion to Designate Claim 1 of the '529 Patent as Corresponding to the Count

One issue remains unresolved: Lilly asks this court to vacate the Board's dismissal of Lilly's motion under 37 C.F.R. § 1.633(c)(3) to redefine the interfering subject matter by designating claim 1 of the '529 patent as corresponding to the count, because Lilly believes the Board manifestly erred by not definitively construing the claim before applying the two-way test. While in many cases this proposition is correct, for the reasons given below, it is possible under the particular circumstances of this case for the Board to dismiss the motion to designate claim 1 of the '529 patent as corresponding to the count even if the claim is not definitively construed.

"A count defines the interfering subject matter between two or more applications or between one or more applications and one or more patents." 37 C.F.R. § 1.601(f). Typically, the PTO determines which claims correspond to the count in order to determine the subject matter of the interference. Id. ("Any claim of an application or patent that is designated to correspond to a count is a claim involved in the interference . . . ."); id. § 1.603. In determining whether it is proper to designate an application or patent claim to correspond to a count, the pertinent inquiry is whether that "claim defines the same patentable invention as another claim whose designation as corresponding to the count the

moving party does not dispute." Id. § 1.637(c)(3)(ii). In that regard, what constitutes the "same patentable invention" is defined by 37 C.F.R. § 1.601(n), which was formulated to determine the extent of interfering subject matter as between applications (or a patent application and an issued patent) of potentially conflicting parties. See In re Van Geuns, 988 F.2d 1181, 1185 (Fed. Cir. 1993). Accordingly, the two-way test promulgated pursuant to 37 C.F.R. § 1.601(n), as discussed above, Part III.B, supra, is applied to determine whether a claim is properly designated to correspond to the count.

That the Board failed definitively to construe claim 1 of the '529 patent is plain enough. To the extent that any procedural error occurred, however, we conclude that the Board did not commit reversible error in this case because the Board applying the two-way test found that, whether construed broadly or narrowly, claim 1 of the '529 patent does not define the same patentable invention as the corresponding claims 1-82 and 84-90 of the '663 reissue application, whose correspondence to the count Lilly does not dispute. The Director's two-way test is usefully illustrated by reference to this case.

First, with respect to the species claim construction of claim 1 of the '529 patent proposed by Lilly, the Board found no interference-in-fact because the specific cDNA sequence of claim 1 of the '529 patent does not teach or suggest the cDNA sequences claimed in the corresponding claims of the '663 reissue application. Because the cDNA sequences claimed in the corresponding claims of the '663 reissue application are not anticipated by and not obvious over a narrowly construed claim 1 of the '529 patent (assuming the '529 patent is the prior art), the cDNA sequences claimed in the '663 reissue application do not define the same patentable

invention. Thus, under the species claim construction as proposed by Lilly, the Board found that Lilly failed to carry its burden to show that claim 1 of the '529 patent should be designated as corresponding to the count.

Similarly, with respect to the genus claim construction of claim 1 of the '529 patent proposed by Lilly, the Board found no interference-in-fact because the evidence presented failed to teach or suggest the selection of the cDNA sequences claimed in the corresponding claims of the '663 reissue application from among the vast number of cDNA sequences potentially encompassed by a broadly construed claim 1 of the '529 patent. Because the cDNA sequences claimed in the corresponding claims of the '663 reissue application are not anticipated by and not obvious over a broadly construed claim 1 of the '529 patent (assuming the '529 patent is the prior art), the cDNA sequences claimed in the '663 reissue application do not define the same patentable invention. Thus, under the genus claim construction as proposed by Lilly, the Board also found that Lilly failed to carry its burden to show that claim 1 of the '529 patent should be designated as corresponding to the count.

The Board therefore tested both of Lilly's proposed claim constructions for interfering subject matter. Because neither construction yielded the same patentable invention as any of the corresponding claims of the '663 reissue application, however, it was unnecessary for the Board to adopt either one of the two claim constructions proffered by Lilly as definitive. Accordingly, we hold that the Board did not commit reversible error when it dismissed as moot Lilly's motion to redefine the interfering subject matter by designating claim 1 of the '529 patent as corresponding to the count, because there was no interference-in-fact based on

either of the two claim constructions proposed by Lilly of claim 1 of the '529 patent. Based on this procedure, namely accepting both constructions proposed by Lilly of claim 1 of the '529 patent and finding that upon either claim construction no interference-in-fact need be declared, there was no need by the Board to definitively construe the claim.

IV. CONCLUSION

The issue is not without its difficulties whichever way we turn. Though not the sole permissible one, the Director's interpretation of 37 C.F.R. § 1.601(n) as establishing a two-way test for determining whether two parties claim the same patentable invention is neither plainly erroneous nor inconsistent with the regulation. The discretionary authority granted to the Director in establishing interferences must be given considerable respect and, when it is neither plainly erroneous nor inconsistent with the promulgated regulation, cannot be second-guessed by this court and must be affirmed. We also hold that the Board committed no reversible error in applying the two-way test to determine that the '529 patent and the corresponding claims of the '663 reissue application do not define the same patentable invention. The judgment of the Board is

AFFIRMED.

United States Court of Appeals for the Federal Circuit

02-1610
(Interference No. 104,733)

ELI LILLY & CO.

Appellant,

v.

BOARD OF REGENTS OF THE UNIVERSITY OF WASHINGTON,

Appellee.

LOURIE, Circuit Judge, dissenting.

I agree that the Director has discretion whether or not to declare an interference. The statute, 35 U.S.C. § 135, expressly provides that "Whenever an application is made for a patent which, in the opinion of the Director, would interfere with any pending application, or with any unexpired patent, an interference may be declared." (emphases added). However, that discretion is not unlimited. It is cabined by the requirement that it not be exercised contrary to the statute under which the Director operates the PTO, and, of particular importance here, the Director must exercise his discretion in a manner that complies with the Patent Office rules of practice.

The Board of Patent Appeals and Interferences here declined to declare an interference between Lilly's reissue application and the University of Washington's patent on the ground that a two-way test applies for determining whether the claims presented by the parties create an interference-in-fact, and, under that test, the parties do not claim the same invention. In so holding, the Board relied on its own decision in Winter v. Fujita, 53 USPQ2d 1234 (Bd. Pat. App. & Int. 1999), and its strained interpretation of 37 C.F.R. § 1.601(n) ("Rule 601(n)") set forth therein. The Board also either failed to consider or chose to ignore the fact that, on the record, Lilly is senior to UW.

I believe the Board's action constitutes an abuse of discretion because the language of Rule 601(n) plainly describes a one-way test and does not support a two-way test. While Winter does hold that a two-way test is appropriate, its conclusion, not binding on us, is unsupported by any reasoning. UW and the majority opinion argue that the PTO's comments in promulgating its interference rules should be considered in our interpretation of the rules, but, when they are contrary to their plain meaning, such comments cannot alter the meaning of the rules.

The Board found that there was no interference-in-fact between claims 1-82 and 84-90 of Lilly's U.S. Reissue application 09/185,663, on the one hand, and claims 1 and 3 of UW's issued '529 patent, on the other. Rule 601(j) (i.e., 37 C.F.R. § 1.601(j)) defines the existence of an interference-in-fact in terms of whether or not the parties claim the "same patentable invention," a term that is defined in Rule 601(n). Rule 601(n) reads as follows:

> Invention "A" is the *same patentable invention* as an invention "B" when invention "A" is the same as

> (35 U.S.C. 102) or is obvious (35 U.S.C. 103) in view of invention "B" assuming invention "B" is prior art with respect to invention "A." Invention "A" is a *separate patentable invention* with respect to invention "B" when invention "A" is new (35 U.S.C. 102) and non-obvious (35 U.S.C. 103) in view of invention "B" assuming invention "B" is prior art with respect to invention "A."

(second emphasis added).

In each case, a one-way test is set forth: whether invention A is the same as or is obvious with respect to invention B, assuming B is prior art with respect to A. The rule does not require that B be the same as or obvious with respect to A, or assume that A is prior art with respect to B. Thus, the rule provides a one-way test, not a two-way test, as the Board erroneously held.

In the case before us, the parties agree that UW's claim 3 is patentably distinct from Lilly's claims 1-82 and 84-90, even though the sequences they claim differ from each other only in two codons out of 419 and yield the same peptide product. Hence, they do not claim the same invention and there is no interference-in-fact with respect to those claims.

As for UW's claim 1, the Board did not construe that claim to determine whether it is generic or directed to a species. Although Lilly has not asked us to construe claim 1 as a generic claim, it asserts that it was error for the Board not to construe the claim at all. Claim construction is a matter of law and construction of claim 1 is necessary to the resolution of this appeal. Claim 1 is directed to a nucleic acid plasmid or vector comprising cDNA coding for a

specified 419 amino acid sequence shown in Figure 3 of the patent. Given the degeneracy of the genetic code, the parties agree, or at least do not contest, that the indicated 419 amino acid sequence can be coded for by more than 10^{23} different cDNA sequences. Thus, it is clear that claim 1 covers all of those cDNA sequences, and must therefore be construed as generic.

Applying the one-way test clearly set forth by Rule 601(n), UW's generic claim 1 must be held to be the same patentable invention, not because a genus and a species are the same, but because Rule 601(n) refers to 35 U.S.C. § 102 after its reference to "same invention," and thereby indicates that the phrase "same patentable invention" encompasses the concept of "is anticipated by." Lilly, on the present record, would be the senior party were an interference to be declared. Clearly, the species in Lilly's prior filed claims anticipates UW's later-filed generic claim. If an interference were to be declared, UW might antedate Lilly's claim, in which case UW's generic claim would remain in force. In that case, however, Lilly's species claim would also remain, because the Board already found the species to be a separate patentable invention with respect to the prior genus. The interference will seem to have been conducted in vain, but the issues will have been settled in accordance with the statutory procedure for resolving a possible conflict of priority between an application (albeit a reissue application) and a patent. If UW does not antedate Lilly's species, then UW's generic claim will be invalid under 35 U.S.C. § 102(g), and the matter will have been settled by the optimal tribunal.

The majority and the Director urge that upholding the Board's decision would avoid unnecessary interferences, which it is said are a burden on the Patent Office. The

answer to that assertion is that it is the job of the Office, which has the expertise to evaluate contending claims for patent, to determine which of those claims have priority and should issue as patents. It is clearly more efficient for even an overburdened Patent Office to make determinations in the arcane world of interferences than for the overburdened courts to do so.

In the present case, affirmance may well lead to a prolonged action in a district court unaccustomed to evaluating interference issues involving cDNA sequences, whereas reversal would result in the more experienced Patent Office determining the respective rights of the parties. Such a determination would likely not be overturned by the courts, see In re Gartside, 203 F.3d 1305, 1316, 53 USPQ2d 1769, 1776 (Fed. Cir. 2000), thereby leaving the first and most important determination of a complex factual matter in the tribunal best able to carry it out.

In summary, the board abused its discretion by interpreting rule 601(n) to require a two-way test for determining when separate patentable inventions are involved and by failing to consider the effective filing dates of the respective parties. I would therefore reverse the board's decision finding no interference-in-fact.

APPENDIX B

The opinion in support of the decision being entered today is not binding precedent of the Board.

Paper 45

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Filed: June 11, 2002

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

BOARD OF REGENTS OF THE
UNIVERSITY OF WASHINGTON
(5,302,529),

Junior Party,

v.

ELI LILLY & CO.

(09/185,663),

Senior Party.

Interference No. 104,733

Before SCHAFER, TORCZON, and TIERNEY,
Administrative Patent Judges.

TIERNEY, Administrative Patent Judge.

JUDGMENT
(PURSUANT TO 37 CFR § 1.640)

This interference is before a motions panel for a decision on preliminary motions. Oral argument took place on April 3, 2002. No transcript of the oral argument is available as the parties did not provide a court reporter.

I. Summary of the Decision

The issues presented in this interference are straightforward. University of Washington ("UW") has requested a judgment of no interference-in-fact. As permitted by the rules, Lilly has requested that, prior to determining the question of no interference-in-fact, we designate an additional UW claim as corresponding to the count.

The Federal Circuit has stated that no interference-in-fact means that there is no interfering subject matter. Thus, no interference-in-fact means that the parties are claiming different patentable inventions, an example of which occurs when the claimed subject matter of a party's patent would not impede the granting of an applicant's claims. As such, the issues raised by the parties are simply a question of whether or not UW's patent claims would prevent the issuance of Lilly's claims.

There is a rebuttable presumption that each claim designated as corresponding to a count defines the same patentable invention as all other claims designated as corresponding to the count. Indeed, 37 CFR § 1.601(j) states that:

> An "interference-in-fact" exists when at least one claim of a party that is designated to correspond to a count and at least one claim of an opponent that is designated to correspond to the count define the same patentable invention.

Accordingly, in analyzing the question of no interference-in-fact, we compare a party's corresponding claims to an opponent's corresponding claims. Specifically, we presume that the subject matter of a party's corresponding claims are "prior art" to an opponent's corresponding claims in order to determine whether or not the parties invented the same patentable invention. Where a party's corresponding claims are separately patentable from an opponent's corresponding claims, a judgment of no interference-in-fact is appropriate.

Presently, UW is involved in this interference on the basis of UW claim 3, a "species" claim. Lilly has requested that UW claim 1, a "genus" claim, be added to the interference as corresponding to Count 1, the sole count in the interference.

UW's corresponding "species" claim does not anticipate or render obvious any of Lilly's corresponding claims. Nor would UW's "genus" claim, should it correspond, anticipate or render obvious any of Lilly's corresponding claims. Accordingly, UW's species and genus claims are not an impediment to granting Lilly's corresponding claims. As such, we grant UW's motion for no interference-in-fact.

The parties have entered into a vigorous dispute as to the relative merits of the Board's precedential decision in *Winter v. Fujita*, 53 USPQ2d 1234 (Bd. Pat. App. & Int.

1999). As the questions presented in this interference do not require our reliance on any issue resolved in Winter, we need not address the parties' comments regarding that decision.

II. The Technology in Question

Generally, the technology involved in this interference relates to cDNA that codes for a polypeptide ("protein") having human protein C activity. Protein C is a zymogen, or inactive precursor, of a plasma serine protease, activated protein C ("APC"). Specifically, protein C is formed as a single-chain polypeptide that undergoes processing to form a two-chain molecule having a heavy chain and a light chain that are connected via disulfide bonds. This two-chain intermediate is converted to APC by cleaving a 12-residue peptide from the heavy chain. APC plays a critical role in the regulation of blood coagulation as it represents a physiological mechanism for blood anticoagulation.[1]

To understand the nature of cDNA it is necessary to understand the function of DNA. DNA ("deoxyribonucleic acid") is the blueprint of an organisms genetic makeup as it is the primary genetic material. In an organism, a portion of DNA, a gene, may undergo transcription to form mRNA (messenger ribonucleic acid). The mRNA in turn, may then be translated to form a polypeptide, e.g., an enzyme or a structural protein.

DNA is the term used to represent the complex macromolecules made up of nucleotide units. A nucleotide

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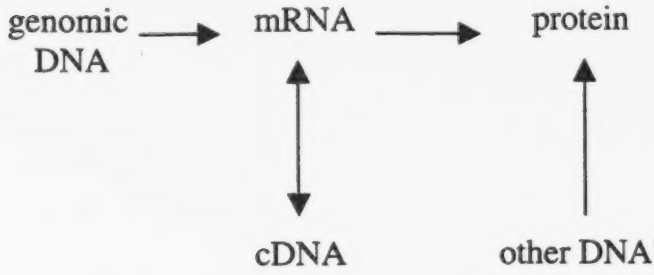
[1] A detailed discussion of the mechanism by which protein C down regulates blood coagulation is provided in Bang et al., U.S. Patent No. 4,775,624. (Ex 1018).

unit is characterized by a specific combination of a base, a sugar and a phosphoric acid residue. There are four different nucleotide units in DNA: adenine ("A"), guanine ("G"), cytosine ("C") and thymine ("T").

As explained in *In re Deuel*:

> A sequential grouping of three such nucleotides (a "codon") codes for one amino acid. A DNA's sequence of codons thus determines the sequence of amino acids assembled during protein synthesis. Since there are 64 possible codons, but only 20 natural amino acids, most amino acids are coded for by more than one codon. This is referred to as the "redundancy" or "degeneracy" of the genetic code.
>
> DNA functions as a blueprint of an organism's genetic information. It is the major component of genes, which are located on chromosomes in the cell nucleus. Only a small part of chromosomal DNA encodes functional proteins.
>
> Messenger ribonucleic acid ("mRNA") is a similar molecule that is made or transcribed from DNA as part of the process of protein synthesis. Complementary DNA ("cDNA") is a complementary copy ("clone") of mRNA, made in the laboratory by reverse transcription of mRNA. Like mRNA, cDNA contains only the protein-encoding regions of DNA. Thus, once a cDNA's nucleotide sequence is known, the amino acid sequence of the protein for which it codes may be predicted using the genetic code relationship between codonsand amino acids. The reverse is not true, however, due to the degeneracy of the code.

Many other DNAs may code for a particular protein. The functonal relationships between DNA, mRNA, cDNA, and a protein may conveniently be expressed as follows:



In re Deuel, 51 F.3d 1552, 1554, 34 USPQ2d 1210, 1211 (Fed. Cir. 1995).

III. Findings of Fact

1. Real Parties in Interest

a. Junior Party

F1. University of Washington ("UW") is the owner of the entire right, title and interest in the involved U.S. Patent No. 5,302,529 ("'529"). Zymogenetics, Inc. is the exclusive licensee of the '529 patent. (Paper No. 11, Notice as to Real Parties In Interest, p. 2).

b. Senior Party

F2. Eli Lilly & Co. ("Lilly") is the real party in interest in the involved U.S. Reissue Patent Application 09/185,663. (Paper No. 5, Eli Lilly & Co. Identification of Real Party in Interest, p. 2).

2. Accorded Priority Benefit

a. Junior Party

F3. UW's involved U.S. Patent No. 5,302,529 issued on April 12, 1994, based upon U.S. Application No. 07/512,961, filed April 23, 1990. Solely for the purposes of priority, UW `529 has been accorded benefit of the filing date of:

> U.S. Patent No. 4,968,626, issued November 6, 1990, based upon U.S. Application 06/766,109, filed August 15, 1985.

(Notice Declaring Interference, Paper No. 1, p. 3).

b. Senior Party

F4. Lilly's involved `663 reissue application is based upon U.S. Patent No. 4,775,624, which issued on October 4, 1988 from U.S. Application 06/699,967, filed February 8, 1985. (Notice Declaring Interference, Paper No. 1, p. 3).

3. The Count and Claim Correspondence

F5. Count 1, the sole count in the interference, is claim 3 of UW's U.S. Patent No. 5,302,529.

UW '529 claim 3 reads as follows:

3. The plasmid or transfer vector of claim 1, comprising the cDNA sequence of FIG. 3, from bp 127 to bp 1383.

F6. The claims of the parties are as follows:

UW: 1-4

Lilly: 1-82 and 84-90

The claims of the parties that have been designated as corresponding to Count 1 are:

UW: 3

Lilly: 1-82 and 84-90

The claims of the parties that were not designated as corresponding to Count 1 are:

UW: 1, 2 and 4

Lilly: None

(Notice Declaring Interference, Paper No. 1, p. 4).

4. Relevant Facts Admitted By Lilly

a. Differences between the cDNA Sequence of UW Claim 3 and Lilly's Claimed Sequences

Lilly has admitted, among other things, the following material facts presented by UW.

F7. The human protein C cDNA sequence of UW claim 3, from by 127 to by 1383 of Foster's Fig. 3, encodes a protein of 419 amino acids, which is a precursor of protein C. (UW Preliminary Motion 1, Paper No. 17, p. 2, 14; Lilly Opposition 1, Paper No. 27, p. 2, ¾, admitting first sentence of UW fact 4.)

F8. Comparing the sequence of UW Fig. 3, by 127 to by 1383, with the pertinent portions of the cDNA sequence of Lilly claim 1, two nucleotide differences are revealed in the coding region:

> 1) UW Fig. 3, nucleotide 423 (third position of codon 99) is thymine ("T"), whereas Lilly's is guanine ("G").
> 2). UW Fig. 3, nucleotide 768, (third position of codon 214) is cytosine ("C"), whereas Lilly's is thymine ("T").

(Paper No. 17, p. 3, ¶6; Paper No. 27, p. 3, admitting UW facts 6-16.) Both Lilly and UW's cDNA sequences are said to encode for human protein C. (Paper No. 27, additional facts ¶¶4, 6 and 7).

F9. The nucleotide variations between UW's Fig. 3 cDNA sequence and the sequence of Lilly claim 1 may be a DNA polymorphism. A polymorphism is defined as one of two different but normal nucleotide sequences existing at a particular site in DNA. The polymorphism may exist in the same individual, e.g., a heterozygous individual or among different individuals, and may encode the same or a different amino acid sequence. (Paper No. 17, pages 2-3, ¶7; Paper No. 27, p. 3, admitting UW facts 6-16.)

F10. According to several of Lilly's named inventors the variations between Lilly's sequence and UW's "may represent a true genetic variant." (Paper No. 17, page 4, ¶8; Paper No. 27, p. 3, admitting UW facts 6-16.)

F11. In seeking to provoke an interference with UW's `529 patent, Lilly represented to the reissue application examiner that:

> . . . it is very likely that the actual Foster [UW] sequence is identical to the corresponding Bang [Lilly] sequence. Indeed, the sequence deposited by Foster in GenBank is **identical** to the corresponding sequence in claim 1 of the Bang application.

Lilly also informed the examiner that:

> *The Differences Between the Bang and Foster Sequences are Probably Foster Mistakes*
>
> As the Patent Office has recently recognized, it is well known that sequencing errors are a common problem in molecular biology. [omitted footnote] Evidence supporting the conclusion that the differences between the Bang and Foster sequences are due to sequencing errors by Foster may be found within the Foster patents themselves: the protein C DNA sequences shown in Figure 2 of Foster contains only one of the base differences: that at position 99. Further evidence may be found in the publications of Foster. Specifically, Foster published articles in the *Proceedings of the National Academy of Sciences* that showed DNA sequences matching both Patent Figure 3 (two base differences) and Figure 2 (one base difference). [omitted footnote] Later, Foster made a deposit of their protein C DNA sequence in GenBank; this deposited sequence is **identical** to the sequence of the Bang application.
>
> * * *

> Applicants submit that this evidence, when viewed as a whole, clearly supports the conclusion that the two nucleotide differences in the Foster
>
> sequence are due to sequencing errors, and not due to true differences in cDNA sequence.

(Paper No. 17, pages 6-8, ¶13, bold emphasis added; Paper No. 27, p. 3, admitting UW facts 6-16.)

F12. GenBank is a publicly accessible database of nucleic acid sequences. According to a review article published in 1985, it was GenBank's practice during the 1980's to gather nucleic acid sequences for their database from published scientific literature. (Paper No. 17, p. 8, ¶14; Paper No. 27, p. 3, admitting UW facts 6-16.)

F13. Lilly advised the reissue application examiner that Lilly's sequence was deposited with GenBank under Accession Number X02750. Specifically, Lilly informed the examiner that there is "absolute similarity" between the sequence in Lilly's '663 reissue application and the GenBank X02750 sequence. (Paper No. 17, p. 8, ¶16; Paper No. 27, p. 3, admitting UW facts 6-16.)(Paper No. 17, p. 8, ¶16; Paper No. 27, p. 3, admitting UW facts 6-16.)

F14. Lilly informed the reissue application examiner that GenBank Sequence NM_000312 was UW's protein C DNA sequence. (Paper No. 17, p. 9, ¶17; Paper No. 27, p. 3, fact 17, stating that Lilly had a good faith belief that its statements regarding the origins of UW's sequences were true and if Lilly was in error, the errorwas inadvertent.)

F15. Lilly's reissue prosecution statements that Foster deposited the NM_0003212 are **mistaken**. The record

demonstates that the NM 0003212 sequence was derived from Lilly's X02750 sequence. (Paper No. 17, p. 10, ¶20; Paper No. 27, p. 3, admitting UW facts 18-21).

b. Coding Sequence Unpredictability

F16. Even if one predicted the existence of at least one DNA polymorphism in a gene, one could not predict where in the coding sequence the difference(s) would occur, how many differences would occur, or what the differences would be. As such, provided with the coding sequence of a single gene, one of ordinary skill in the art could not predict with accuracy the number or location of DNA differences between the genes of different people encoding the same protein. (Paper No. 17, p. 5, ¶10; Paper No. 27, p. 3, admitting UW facts 6-16.)

F17. The two codon differences between UW's claim 3 sequence and Lilly's claim 1 sequence could not have been predicted in advance based on knowledge of either Lilly's nucleotide sequence or Lilly's amino acid sequences. (Paper No. 17, p. 5, ¶11; Paper No. 27, p. 3, admitting UW facts 6-16.)

F18. One of ordinary skill in the art could not have predicted the particular DNA sequence of UW claim 3 based on the amino acid sequence of human protein C light chain, such as that recited in Lilly claim 81, or a particular DNA encoding that amino acid sequence, such as that provided in Lilly claim 82. (Paper No. 17, p. 11, ¶21; Paper No. 27, p. 3, admitting UW facts 18-21).

IV. Opinion

An Administrative Patent Judge ("APJ") declared this interference based, in part, on statements made during the examination of Lilly's reissue application. UW claim 3 is directed to a plasmid or transfer vector comprising a string of base pairs identified in the cDNA sequence of *UW Figure 3*. During the prosecution of Lilly's reissue application, Lilly represented to the examiner that Foster ("UW") had deposited a nucleotide sequence encoding protein C that was ***identical*** to the corresponding sequence of Lilly's claim 1. (UW Preliminary Motion 1, Paper No. 17, pages 6-8, ¶13, Lilly Opposition 1, Paper No. 27, p. 3, admitted facts 6-16). According to Lilly:

> Applicants submit that this evidence, when viewed as a whole, clearly supports a conclusion that the two nucleotide differences in the Foster sequence [*UW Figure 3*] are due to sequencing errors, and not due to true differences in cDNA sequence.

Id.

When the interference was declared, the Office was unaware that the purported "Foster sequence," Accession No. NM_00312 was ***Lilly's own sequence***. (Paper No. 17, p. 9, ¶¶17, 20; Paper No. 27, p. 3, Lilly stated that it had a good faith belief that its statements were true and that any error was "inadvertent."). In light of the evidence provided by UW, we find that Lilly's statements regarding the origin of the deposited sequence were incorrect and that the claimed UW species and Lilly species are apparently genetic variants. (See, Paper No. 17, p. 4, ¶8, Paper No. 27, p. 3, admitting facts 6-16).

UW has filed a preliminary motion seeking a judgment of no interference-in-fact based on the differences between the sequence of UW claim 3 and the sequences recited in Lilly's claims. (UW Preliminary Motion 1, Paper No. 17, p. 1). In response to UW's motion, Lilly filed a preliminary motion requesting that the interfering subject matter be redefined to have UW claim 1 designated as corresponding to Count 1. (Lilly Preliminary Motion 1, Paper No. 27, p. 1).[2]

1. What is Required for a Determination of "No Interference-In-Fact"

Both UW and Lilly agree that there is an interference-in-fact when two parties are claiming the same patentable subject matter. The parties, however, disagree as to the test for determining whether the parties claims define the same patentable subject matter.

While 35 U.S.C. § 135(a) sets forth the requirements for declaring an interference, the statute fails to explicitly state the requirements for determining whether there is no interference-in-fact once an interference has been declared. To aid us in our understanding, we look to the United States Patent & Trademark Office's ("USPTO") rules regarding no interference-in-fact. Yet, as the comments to the rules specifically state that USPTO would continue to follow the decisions rendered in *Case v. CPC International, Inc.*,[3] *Aelony v. Arni*,[4] and *Nitz v. Ehrenreich*,[5] we review these

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[2] Rule 633(i) allows a party to respond to a motion for no interference in fact by filing, among other things, a motion under Rule 633(c) to redefine the interfering subject matter.

[3] 730 F.2d 745, 221 USPQ 196 (Fed. Cir. 1984).

[4] 547 F.2d 566, 192 USPQ 486 (CCPA 1977).

decisions prior to our review of the USPTO rules. Notice of Final Rules, 49 Fed. Reg. 48416, 48,421 (Dec. 12, 1984).

A. The Opinions of the Federal Circuit and the Court of Customs and Patent Appeals ("CCPA")

1. *Nitz v. Ehrenreich*

Nitz involved an appeal from the Board of Patent Interferences[6] awarding priority of invention to Ehrenreich. Specifically, the Board awarded priority of invention as to two counts, counts 1 and 2, to Ehrenreich. Nitz appealed the decision arguing, among other things, that there was no interference-in-fact as to either count.

The interference was provoked when senior party Ehrenreich copied, in modified form, claims 3 and 13 of Nitz's U.S. Patent No. 3,552,533. The subject matter of the two copied claims involved carbonized articles having a modifying agent to increase the coefficient of friction of carbon. Of note, count 1 required up to about 48 percent by weight of a friction modifier and count 2 required carbonized layers of filamentary materials.

During the Board proceeding, Nitz argued that the counts did not define common subject matter that was claimed by both parties. In reviewing Nitz's arguments with respect to count 1, the Board recommended to the Commissioner that the interference be dissolved.

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[5] 537 F.2d 539, 190 USPQ 413 (CCPA 1976).

[6] The decision in Nitz occurred prior to the merger of the Board of Interferences with the Board of Patent Appeals.

Specifically, the Board viewed Nitz's limitation of up to 12 weight percent of a friction modifier as defining a patentably distinct invention from that of count 1, which required up to about 48 weight percent of the friction modifier. The Commissioner, however, disapproved of the recommendation as the Commissioner was of the opinion that the amount of the modifier was not a critical limitation and that there was no basis for Nitz and Ehrenreich's claims to exist in separate patents. As to count 2, the Board determined that the count's failure to recite the term "woundup," as found in Nitz's claimed carbonized layers, was not a patentable distinction.

Additionally, Nitz raised the issue of Ehrenreich's "right to make count 1." As to this issue, the Board determined that Ehrenreich's disclosure was sufficient to support the limitations of the count. Having decided the issues of no interference-in-fact and right to make the counts, the Board awarded priority on both counts to Ehrenreich. Nitz appealed.

In reviewing the question of interference-in-fact and the court's jurisdiction to consider that issue, the CCPA stated:

> The existence of common subject matter defined by the interference count is a prerequisite for an award of priority, i.e., the existence or nonexistence of interfering subject matter goes to the very foundation on which an interference rests. Determination of the presence or absence of interfering subject matter is "logically related" to the jurisdiction-conferring issue of priority because that determination necessarily precedes a priority award.

537 F.2d at 543, 190 USPQ at 416.

As to the question of no interference-in-fact, the CCPA compared the disclosure and claims of Nitz with the count and the disclosure of Ehrenreich. According to the CCPA:

> In the case before us the materiality of the questioned limitation and its variation must be determined in a two-step process wherein the first inquiry is **[1]** whether the variation changes a material aspect of the patentee's invention (here, whether the maximum amount of friction modifier of "up to 12 percent by weight" is a material limitation) and, if that inquiry be decided in the affirmative, the second inquiry is **[2]** whether the variation is itself a material variation (here, whether "up to 48% by weight" results in the counts being drawn to a different invention).

Id. at 544, 190 USPQ at 417.

Conducting the two-step inquiry, the CCPA focused on Nitz's description that at least 80 weight percent carbon was a critical feature of the invention and the limitation that the modifier was present in an amount "up to 12% by weight." Furthermore, the CCPA focused on Ehrenreich's disclosure of using up to 48% by weight modifier, which would allow for a maximum of 52% by weight carbon. *Id.* at 544, 190 USPQ at 417-18.

The CCPA determined that Nitz's claim recitation of "tip to 12% by weight" of a modifier was a material limitation due to the critical nature of having at least 80% carbon. The CCPA then determined that the count language

"up to about 48% by weight" of the modifier was a material variation from Nitz's claimed invention. As such, the CCPA concluded that no interference-in-fact existed with respect to count 1. *Id.* at 545, 190 USPQ at 418.

As to count 2, the only issue on appeal was the materiality of Nitz's recitation that the carbonized layers of filamentary materials were "woundup" layers. The CCPA, however, determined that the structure of woundup layers was known in the prior art and that the limitation was not necessary for the patentability of Nitz's claim. As such, the CCPA determined that Nits "woundup" limitation was not a material limitation of Nitz's claim and that an interference-in-fact existed with respect to count 2.

Nitz is consistent with the principle that there is no interference-in-fact when two parties are claiming "materially" different inventions. Further, *Nitz* is consistent with the principle that, for purposes of no interference-in-fact, claims of different scope can be separate patentable inventions even where one party's claim is literally encompassed by a second party's claim. Specifically, the CCPA found that Nitz's claimed "up to 12% by weight" modifierwas a materially different invention from Ehrenreich's claimed "up to 48% by weight" modifier even though Nitz's claimed amount of modifier was literally encompassed by Ehrenreich's claimed amount of modifier.

2. *Aelony v. Arni*

Aelony concerned an appeal from a decision of the Board awarding priority of invention to Arni, the senior party. The subject matter of the interference was a method for purifying malononitrile. In particular, both parties treated an impure malononitrile with a conjugated diene in a Diels-

Alder reaction to aid in the removal of impurities. Of note, Aelony taught the use of cyclopentadiene, a conjugated diene. In contrast, Arni did not specifically describe or claim cyclopentadiene as a suitable Diels-Alder reaction component for the removal of impurities. Rather, Arni specifically described eight other materials having conjugated double bonds as suitable for undergoing a Diels Alder reaction for the removal of impurities. *Aelony v. Arni*, 547 F.2d 566, 567, 192 USPQ 486, 487 (CCPA 1977).

Before the Board, neither Aelony nor Arni took testimony. Rather, Aelony argued that there was no interference-in-fact between the parties. Specifically, Aelony argued that, for the purification method in dispute, cyclopentadiene was patentably distinct from the eight materials described by Ami. *Id.* at 568, 192 USPQ at 488. The Board did not agree. According to the Board, both parties carried out substantially the same process. Moreover, the Board found that Aelony's patentable distinctiveness argument was unsupported by the evidence. As such, the Board rejected Aelony's no interference-infact argument and awarded priority to senior party Ami. *Id.* at 568, 192 USPQ at 488.

In reviewing the merits of Aelony's appeal, the CCPA specifically rejected Aelony's argument that there was no interference-in-fact. The CCPA agreed with the Board "that the test of interference-in-fact is not whether two sets of claims overlap, but whether they are patentably distinct from each other." *Id.* at 570, 192 USPQ at 490 (bold emphasis added). According to the CCPA, the law contemplates that "where different inventive entities are concerned - that only one patent should issue for inventions which are either identical to or not patentably distinct from **each other**." *Id.* (bold emphasis added). The CCPA went on to state that

"[m]oreover, we believe that there is ample precedent from this court for framing the test of interference in fact in terms of whether two sets of claims are patentably distinct from **each other**." *Id.* (bold emphasis added).

On the facts presented, the CCPA determined that "**both parties are claiming the same inventive concept**" and rejected Aelony's argument that there was no interference-in-fact. *Id.* (bold emphasis added). In particular, the CCPA noted that both parties carried out the same process in which a conjugated diene material reacted with impurities according to the Diels-Alder reaction. Further, there was no dispute that the cyclopentadiene of Aelony and the eight conjugated dienes of Arni were all common Diels-Alder dienes. *Id.*

The decision in Aelony denied a motion for no interference-in-fact where two parties were claiming patentably indistinct inventions. Specifically, in deciding the question of no interference-in-fact, the CCPA focused its attention on whether or not the parties claims were patentably distinct from **each other**. Where the claims of the parties are not patentably distinct from each other, the parties are claiming the same inventive concept and it is understood that only one patent should issue.

3. *Case v. CPC International, Inc.*

Case involved an appeal from a decision of a district court in a civil action under 35 USC §146 upholding the award of priority to CPC International, Inc., ("CPC") in an interference proceeding in the USPTO. The subject matter in

the interference was directed to polyether polyols that consisted essentially of oxyalkylated polyalcohols and oxyalkylated polysaccharides. *Case v. CPC Int'l, Inc.*, 730 F.2d 745, 747, 221 USPQ 196, 198 (Fed. Cir. 1984).

The interference was provoked by CPC. To provoke the interference, CPC copied Case's patented claims. Of note, Case's patented claims specified that an oxyalkylated polyalcohol was present in an amount of 10 to 95% by weight and that an oxyalkylated polysaccharide was employed in an amount of 5 to 95% by weight. During examination, CPC's claims were rejected as lacking sufficient written descriptive support under 35 U.S.C. § 112, 1st paragraph, for the copied weight limitations. The examiner, however, advised CPC to submit claims directed to "a polyether polyol which is the reaction product of starch and the various disclosed derivatives thereof with glycerin and propylene oxide." *Id.* In response to the examiner's rejection of the copied claims, CPC canceled the copied claims and submitted new claims that complied with the examiner's suggestion. *Id.* The newly added CPC claims, however, did not recite a particular weight limitation for the two oxyalkylated components. Moreover, when the interference was declared, the counts did not recite the weight limitations found in Case's patented claims.

Case presented numerous arguments challenging both the district court and the Board's award of priority to CPC. Of interest, Case argued that no interference-in-fact existed between Case's claims and CPC's. According to Case, the question of no interference-in-fact turned on whether or not the weight limitations present in Case's claims, but not CPC's

claims, were material. The Federal Circuit agreed with this analysis.[7] *Id.* at 750, 221 USPQ at 200.

According to the Federal Circuit, the question of materiality of the omitted limitations was one of fact. *Id.* The Court noted that both the district court and the Board had determined that the omitted weight limitations were not material as the range of proportions was quite broad and that Case's prosecution history demonstrated that the omitted limitations were not pertinent to patentability.

Additionally, Case argued that there was no interference-in-fact as the counts were unpatentable. Having reviewed Case's arguments, the Federal Circuit stated that:

> **No interference in fact means that there is no interfering subject matter, that Case's patent is no impediment to granting CPC the claims of its application.** It was Case's burden to prove that CPC claims a different invention from his own. Case cannot carry that burden with argument that the counts are unpatentable.

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[7] Specifically, the Federal Circuit stated:

> Case challenges the declaration of the interference on the ground that no interference in fact exists. Relying on *Nitz v. Ehrenreich*, 537 F.2d 539, 190 USPQ 413 (CCPA 1976), Case argues that the question of interference in fact turns on whether or not the weight limitations present in the claims of Case's patent but omitted from the counts are material. We agree with this analysis but we see no departure by the board or the court in stating the law or applying it to the facts of this case.

Id.

Id. (emphasis added). The Federal Circuit also stated that "[i]n sum, since the Case patent and the CPC application contain interfering subject matter, an interference proceeding was appropriate." *Id.* at 752, 221 USPQ at 202. The Court then went on to uphold the decision awarding priority of invention to CPC based upon its earlier application. *Id.*

As apparent from the decision in Case, the question of no interference-in-fact turns on whether or not the parties claims are "materially" different. The question of "material" differences being one of fact. Further, Case specifies that no interference-in-fact exists where one party's patent does not impede the grant of another party's claims.

4. Summary of the CCPA and Federal Circuit Opinions on the Question of No Interference-in-Fact

An interference in fact involves interfering subject matter. As shown by the above decisions, there is no interfering subject matter, and thus, no interference-in-fact when the parties are claiming different patentable inventions. For example, there is no interference-in-fact when it is demonstrated that a party's claims are no impediment to the granting of an opponents claims. *Case*, 730 F.2d at 750, 221 USPQ at 200.

The cases analyzed above, *Nitz, Aelony* and *Case* and our interpretations thereof are all consistent with the no interference-in-fact decisions in *Almasi v. Strauss*, 589 F.2d 523, 200 USPQ 511 (CCPA 1979), and *Brailsford v. Lavet*, 318 F.2d 942, 138 USPQ 28 (CCPA 1963) as well as the interference-in-fact decision in *McCabe v. Cramblet*, 65 F.2d 459, 18 USPQ 71 (CCPA 1933).

B. The USPTO Rules and the Comments to the Rules Provide that No Interference-in-Fact Exists for Patentably Distinct Inventions

The interference rules were revised in 1984 to implement the interference provisions of the Patent Law Amendments Act of 1984 (Public Law 98-622). Notice of Final Rule, Patent Interference Proceedings, 49 Fed. Reg. 48416 (Dec. 12, 1984). As part of the rule revision, the Commissioner (now Director) promulgated several rules regarding the existence of an interference-in-fact. For example, the Commissioner promulgated 37 CFR Section 1.601(j)(definition of an interference-in-fact), Section 1.601(n)(definition of same and separate patentable inventions) and Section 1.633(b), which authorized parties to file preliminary motions for judgment on the ground that there is no interference-in-fact.

In their present form, Rules 601(j), 601(n) and 633(b) read as follows:

> Rule 601(j) An *interference-in-fact* exists when at least one claim of a party that is designated to correspond to a count and at least one claim of an opponent that is designated to correspond to the count define the same patentable invention.
>
> Rule 601(n) Invention "A" is the *same patentable invention* as an invention "B" when invention "A" is the same as (35 U.S.C. 102) or is obvious (35 U.S.C. 103) in viewof invention "B" assuming invention "B" is prior art with respect to invention "A". Invention "A" is a *separate patentable invention* with respect to invention "B"

> when invention "A" is new (35 U.S.C. 102) and non-obvious (35 U.S.C. 103) in view of invention "B" assuming invention "B" is prior art with respect to invention "A".
>
> Rule 633(b) A motion for judgment on the ground that there is no interference-in-fact. A motion under this paragraph is proper only if the interference involves a design application or patent or a plant application or patent or no claim of a party which corresponds to a count is identical to any claim of an opponent which corresponds to that count. See §§1.637(a). When claims of different parties are presented in "means plus function" format, it may be possible for the claims of the different parties not to define the same patentable invention even though the claims contain the same literal wording.

Rules 601(j) and (n): 49 FR 48416, Dec. 12, 1984, effective Feb. 11 , 1985; 50 FR 23123, May 31, 1985; revised, 60 FR 14488, Mar. 17, 1995; Rule 633(b): 49 FR 48416, Dec. 12, 1984, added effective Feb. 11, 1985; 50 FR 23124, May 31, 1985; revised, 60 FR 14488, Mar. 17, 1995, effective Apr. 21, 1995.

While the rules explicitly define when an *interference-in-fact* exists, the rules do not explicitly define "no" interference-in-fact. The comments to the rules, however, provide that the USPTO will continue to follow the decisions rendered in *Nitz, Aelony* and *Case*. Notice of Final Rules, 49 Fed. Reg. 48416, 48421 (Dec. 12, 1984). As provided above, these three decisions demonstrate that the test for no interference-in-fact is grounded in patentable distinctness. *Nitz*, 537 F.2d at 545, 190 USPQ at 418;

Aelony, 547 F.2d at 570, 192 USPQ at 490; *Case*, 730 F.2d at 750, 221 USPQ at 200. As such, a party may demonstrate that no interference-in-fact exists between two parties by proving that a first party's claim(s) are patentably distinct from the second party's claim(s).

The test for patentable distinctness is set forth in Rule 601(n), which states that an invention "A" is a separately patentable invention, i.e. patentably distinct, with respect to invention "B" when invention "A" is novel and non-obvious in view of invention "B" assuming invention "B" is prior art with respect to invention "A". For example, party A's claims are patentably distinct, i.e., separately patentable, when the party A's claims are no impediment to the granting of the opponents claims. *See, e.g., Nitz*, 537 F.2d at 544-45, 190 USPQ at 417-18 (No interference-in-fact where "up to 48%" modifier did not interfere with "up to 12%" modifier); *Case*, 730 F.2d at 750, 221 USPQ at 200 ("No interference in fact means that there is no interfering subject matter, that Case's patent is no impediment to granting CPC the claims of its application.").

C. Lilly's Species Anticipates Dominating Genus Theory of Interference-in-Fact Lacks Merit

Lilly argues that for an interference in fact, the interference rules and comments require nothing more than a "species anticipates dominating genus" determination. Thus, according to Lilly, its claimed species is the "same patentable invention" as UW's claimed genus based on the fact that its species would anticipate UW's genus. Lilly states that the comments specifically inform the public that the test under Rule 601(n) for determining the "same" patentable

invention could not be applied two ways, i.e. a party need only demonstrate "one-way" anticipation or obviousness for an interference-in-fact. Specifically, Lilly has argued that:

> The regulations of the PTO, 37 CFR §1.601(n), having the force and effect of law, require nothing more than the "species anticipates dominating genus" determination to establish the existence of an interference-in-fact. Indeed, the official commentary issued by the PTO at the time the rules were adopted made dear that the test for the "same patentable invention" under 37 CFR §1.601 (n) could not be applied two ways. 49 FR 48416 at 48434 (Dec. 12, 1984). ***As stated by the PTO in the administrative history for the regulations, the "same patentable invention' [test]. . . under §1.601(n) . . . [is] not intended to be 'applied in a mutuartysense.***'" [Footnote omitted].

(Lilly Preliminary Motion 1, Paper No. 22, p. 5, emphasis added). Additionally, responding to comments from UW, Lilly stated:

> In response to a specific question posed by one commentator in 1984 asking whether the PTO's proposed Rule 1.601 (n) would involve a one-way or two-way patentability determination, the Office responded in unequivocal terms that a one-way test would be applied. Notice of Final Rules, 49 Fed. Reg. 48,416, 48,433 (1984). Six years later this rule was restated by the Board in Chiong v. Roland, 17 U.S.P.Q.2d 1541, 1544 (Bd. Pat. App. & Int. 1990)("As pointed out in the Notice, supra at 48433, ***the standard of patentability will not be applied on a 'mutual basis***.'")

(Lilly Reply 1, Paper No. 30, pages 8-9, emphasis added). This panel has reviewed the comments to the rules and finds no merit in Lilly's "species anticipates dominating genus" test.

Lilly has relied upon two specific comments to the rules. The comments may be found at pages 48,433-48,434 of the Notice of Final Rules, 49 Fed. Reg. 48,416 (Dec. 12, 1984). Provided below are the full paragraphs ((1) & (2)) from which Lilly's quoted material is derived:

> (1) With respect to paragraph (1) of the comment, the standard of patentability will not be applied "on a mutual basis." ***Thus, if a species is patentable over a genus, the species is a "separate patentable invention" from the genus***. Compare *In re Taub*, 348 F.2d 556, 146 USPQ 384 (CCPA 1965) (fluorine species might be patentable over genus of Markush group of hydrogen and halogen). A first count to a genus and a second count to a species which is patentable over the genus may properly appear in an interference. See e.g., Example 4. The comment suggests that if "such mutuality is not applied * * * then a number of irreconcilable anomalies * * * will be manifest." The urged "irreconcilable anomalies" are not readily apparent to the PTO.

(Fed. Reg., p. 48433, underline emphasis added denotes Lilly's cited commentary, bold emphasis added to highlight application of Rule 601 (n) for genus/species situations).

> (2) Analysis of Commentator's Example A. Example A does not describe any practice under these rules, because "same patentable invention"

> and "separate patentable invention" under § 1. 601(n) are not intended to be "applied in a mutuality sense." ***Where a first count is to a genus and a second count is to a species within the scope of the genus, there maybe two counts if the species is separately patentable from the genus***. The species is "invention A" referred to in § 1.601(n); the genus is "invention B" referred to in § 1.601(n).

(Fed. Reg., p. 48434, underline emphasis added denotes Lilly's cited commentary, bold emphasis added to highlight application of Rule 601(n) for genus/species situations).[8]

The comments to the rules regarding the test for "same or separate patentable inventions" are highly relevant and material to the issues raised in this interference as they inform the public that a genus and a patentably distinct species are separate patentable inventions. If the rule were only applied in the manner suggested by Lilly, i.e., nothing more than species anticipates dominating genus, then the

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[8] While not specifically mentioned by Lilly, Lilly's relied upon comments were written in response to questions concerning whether or not the standard of patentability would be applied on a mutual basis in determining whether to add an additional count. Each count, of course, must be directed to a separate patentable invention. 37 CFR §1.601(f). In other words, the comments responded to a question of whether the USPTO would require that Invention A be separately patentable from Invention B considered as prior art **and** Invention B be separately patentable from Invention A considered as prior art), in order for an interference to have both a species count and a genus count. The answer to this was no. Notice of Final Rules, 49 Fed. Reg. 48,416, 48432-434 (Dec. 12, 1984). Note, the test for no interference-in-fact and the addition of new count is essentially the same, i.e., patentable distinctness. *See, e.g., Hester v. Allgeier*, 646 F.2d 513, 521, 209 USPQ 370, 378 (CCPA 1982).

comments to the rule that a species that is patentable over a genus is a "separate patentable invention" from the genus would make no sense. Specifically, Lilly's argument would have us determine that the species and dominating genus defined both the same patentable invention and, at the same time, a separate patentable invention. Consistent with the precedential Federal Circuit and CCPA opinions mentioned above, the comments to rules explicitly provide that a patentably distinct species and a dominating genus are ***separately patentable*** inventions.

2. Lilly and UW's Corresponding Gaims Are Separate Patentable Inventions As UW's Corresponding Claims Do Not Impede the Grant of Lilly's Corresponding Claims

The test for no interference-in-fact is whether or not the parties are claiming separately patentable inventions. In applying this test, we begin with a comparison of the parties' corresponding claims as there exists a rebuttable presumption that each claim designated to correspond to a count defines the same patentable invention as all other claims designated to correspond to the count. See, e.g., *Orikasa v. Oonishi*, 10 USPQ2d 1996, 2004 (Comm'r Pat. & Trademark 1989).

Count 1 is the sole count in interference. As declared, UW claim 3 and Lilly claims 1-82 and 84-90 correspond to Count 1. Additionally, Lilly has requested that UW claim 1 be designated as corresponding to Count 1. For purposes of determining if there is no interference-in-fact between the parties, we will assume that Lilly is correct in stating that UW claim 1 corresponds to Count 1. Accordingly, we compare UW claims 1 and 3 with Lilly's corresponding

claims to determine whether the parties are claiming separately patentable inventions.

A. Anticipation and Obviousness

A prima facie case of obviousness is established when the teachings of the prior art would have suggested the claimed subject matter to a person of ordinary skill in the art with a reasonable likelihood of success of achieving the suggested invention. *In re Dow Chem.*, 837 F.2d 469, 473, 5 USPQ2d 1529, 1531 (Fed. Cir. 1988). Any motivation or suggestion to modify the prior art references must flow from some teaching in the art that suggests the desirability or incentive to make the modification needed to arrive at the claimed invention. *In re Napier*, 55 F.3d 610, 613, 34 USPQ2d 1782, 1784 (Fed Cir. 1995); *In re Gorman*, 933 F.2d 982, 986-87, 18 USPQ2d 1885, 1888, (Fed. Cir. 1991).

A claim to a specific cDNA is not made obvious by mere knowledge of a desired protein sequence and methods for generating the various cDNA that have the potential to encode that protein. *Cf., Regents of the Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559, 1567, 43 USPQ2d 1398, 1405 (Fed. Cir. 1997)("We had previously held that a claim to a specific DNA is not made obvious by mere knowledge of a desired protein sequence and methods for generating the DNA that encodes that protein."); *In re Deuel*, 51 F.3d 1552, 1558, 34 USPQ2d 1210, 1215 (1995)("A prior art disclosure of the amino acid sequence of a protein does not necessarily render particular DNA molecules encoding the protein obvious because the redundancy of the genetic code permits one to hypothesize an enormous number of DNA sequences coding for the protein."); *In re Bell*, 991 F.2d 781, 787, 26 USPQ2d 1529, 1531 (Fed. Cir. 1993)("It may be true that,

knowing the structure of the protein, one can use the genetic code to hypothesize possible structures for the corresponding gene and that one thus has the potential for obtaining that gene. . . Therefore, given the nearly infinite number of possibilities suggested by the prior art, and the failure of the cited prior art to suggest which of those possibilities is the human sequence, the claimed sequences would not have been obvious.").

Anticipation is the epitome of obviousness. *Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542, 1548, 220 USPQ 193, 198 (Fed. Cir. 1983) (citing *In re Fracalossi*, 681 F.2d 792, 215 USPQ 569 (CCPA 1982)). Anticipation is established only if each and every element of a properly construed claim is found, either expressly or inherently described, in a prior art reference. *PPG Indus., Inc. v. Guardian Indus. Corp.*, 75 F.3d 1558, 1566, 37 USPQ2d 1618, 1624-1625 (Fed. Cir. 1996).

B. UW Claim 3 is Patentably Distinct from Lilly's Corresponding Claims

UW claim 3 is directed to a plasmid or transfer vector that comprises the cDNA sequence depicted in UW Figure 3, from base pair 127 to base pair 1383. Lilly claim 1 corresponds to Count 1 and requires a constructed DNA compound that encodes a polypeptide with human protein C activity wherein the coding strand comprises several distinct cDNA species. Lilly claims 2-75, 77-80 and 84-88 all depend from Lilly claim 1 or require a DNA compound of Lilly claim 1. Of the remaining Lilly corresponding claims, Lilly claim 76 is directed towards several "intermediate" plasmids that lack the protein C cDNA, while Lilly claims 81 and 82 relate to recombinant DNA sequences that comprise

the coding sequence for the active light chain of human protein C. Thus, as it is readily apparent that Lilly's intermediate plasmids are patentably distinct from UW claim 3, the proper comparison for patentable distinctness is between the cDNA species of UW claim 3 and the cDNA species recited in Lilly claim 1 and Lilly claims 81 and 82.[9]

The sequence claimed in UW claim 3 is a cDNA sequence having at least 1257 base pairs, i.e., 419 codons (three base pairs to a codon), that encode a protein of 419 amino acids. For such a sequence, the odds of randomly changing a single codon are 1 in 419, changing any two codons at random is 1 in 175,142 (419 x 418), changing any three codons at random is 7,303,214 (419 x 418 x 417), etcetera. (See generally, Paper No. 17, pages 5-6, ¶ 11).

Comparing the sequence of UW claim 3 (UW Fig. 3, by 127 to by 1383) with the pertinent portions of the cDNA sequence of Lilly claim 1, two nucleotide differences are revealed in the coding region:

1) UW Fig. 3, nucleotide 423 (third position of codon 99) is thymine ("T"), whereas Lilly's is guanine ("G").
2). UW Fig. 3, nucleotide 768, (third position of codon 214) is cytosine ("C"), whereas Lilly's is thymine ("T").

(Paper No. 17, p. 3, ¶6; Paper No. 27, p. 3, admitting UW facts 6-16.). The parties agree that:

---

[9] While Lilly's corresponding claims encompass several distinct species of cDNA, for reasons of convenience we refer to Lilly claims as "species" claims as opposed to "genus" or "subgenus" claims.

> The particular differences in the nucleotide sequences that occur between the sequences of Foster [UW]claim 3 and Bang [Lilly] claim 1 within two different codons could not have been predicted in advance based on knowledge of either Bang's nucleotide or amino acid sequences alone.

(Paper No. 17, p. 5, ¶11; Paper No. 27, p. 3, admitting UW facts 6-16.).

When there is a specific, structurally related prior art compound, the question of obviousness is whether the prior art suggested the specific modifications necessary to achieve the claimed compound. *In re Deuel*, 51 F.3d at 1557-58, 34 USPQ2d at 1214. On the record presented, there is insufficient evidence that Lilly's claimed sequence, taken in combination with the prior art, would have suggested the specific modifications to nucleotide 423 and nucleotide 768 such that one skilled in the art would arrive at the cDNA sequence described by UW claim 3. Additionally, there is insufficient evidence that one skilled in the art presented with the amino add sequence of human protein C would have been guided to form the specific cDNA sequence recited in UW claim 3. *In re Deuel*, 51 F.3d at 1559, 34 USPQ2d at 1215-16 (Due to enormous number of DNA molecules encoding for the protein, disclosure of amino acid sequence did not render particular DNA molecules encoding the protein obvious). We conclude that Lilly claim 1 and UW claim 3 are patentably distinct as Lilly claim 1 does not render UW claim 3 obvious. Furthermore, Lilly claim 1 does not anticipate UW claim 3 as Lilly claim 1, taken in light of the prior art, fails to teach all the limitations of UW claim 3.

Lilly claims 81 and 82 are directed to the coding sequence for the active light chain of human protein C. Lilly

claim 81 does not specifically recite the structure of the coding sequence whereas Lilly claim 82 specifically sets forth the coding strand. The coding strand in Lilly claim 82 contains 465 base pairs, i.e., 155 codons. In contrast, UW claim 3 is directed to the cDNA encoding protein C and contains 1257 base pairs, i.e., 419 codons. The amino acid sequence of human protein C light chain, such as that recited in Lilly claim 81, and a particular DNA encoding that amino acid sequence, such as that provided in Lilly claim 82, do not provide sufficient information for one skilled in the art to predict the particular DNA sequence of UW claim 3. (Paper No. 17, p. 11, ¶21; Paper No. 27, p. 3, admitting UW facts 18-21). As Lilly claims 81 and 82 fail to teach or suggest the cDNA of UW claim 3, we conclude that UW claim 3 is patentably distinct from Lilly claims 81 and 82.

C. Lilly's Corresponding Claims Are Patentably Distinct from UW Claim 1

UW claim 1 is directed to a plasmid or transfer vector that comprises cDNA coding for a human protein C. According to Lilly, there are two possible claim constructions for UW claim 1. (See, Paper No. 30, pages 4-5). First, Lilly contends that UW claim 1 must be construed as "limited to the specific allelic cDNA sequence disclosed in the UW `529 Patent, as is claim 3 of the UW `529 Patent" and that "claim 1 of the UW `529 Patent is essentially equivalent to claim 3 of the UW `529 Patent." (Paper No. 27, p. 7 and p. 9 and Paper No. 30, p. 4). Alternatively, Lilly argues that it is expected that UW will contend that claim 1 is generic and encompasses not only the cDNA sequence that UW discovered, but also the cDNA sequence discovered by Lilly. (See, Paper No. 27, p. 9). It is not necessary for us to determine whether UW claim 1 is as broad or as narrow as

Lilly contends. There is no interference-in-fact under either claim construction. If we construe UW claims 1 and 3 as "essentially equivalent," there is no interference-in-fact as Lilly's corresponding claims do not teach or suggest the cDNA of UW claim 3 and would likewise not teach or suggest an "essentially equivalent" cDNA of UW claim 1. Specifically, Lilly's corresponding claims do not teach or suggest the particular number and location of the polymorphisms in the cDNA of UW claim 3 nor would they teach or suggest a such polymorphisms in a similarly construed claim.

If we construe UW claim 1 to be a generic claim covering any cDNA sequence that encodes human protein C, there is still no interference-in-fact. So construed, UW claim 1 would encompass thousands of possible sequences. Given such a vast number of possible sequences encompassed by a broadly construed UW claim 1, there would need to exist some suggestion or teaching in the prior art that guided one skilled in the art to the specific species claimed by Lilly. *See In re Baird*, 16 F.3d 380, 29 USPQ2d 1550 (Fed. Cir. 1994)(Prior art teaching of "vast number" of possible diphenol compounds did not teach or suggest the selection of Baird's claimed bisphenol A); *In re Belle*, 991 F.2d 781, 26 USPQ2d 1529 (Fed. Cir. 1993)(DNA sequence would not have been obvious in view of prior art reference that taught a vast number of possibilities but did not teach or suggest why, among all those possibilities, one would seek the claimed sequence). The evidence presented fails to teach or suggest the selection of Lilly's claimed cDNA species from among the vast number of potential sequences that would be encompassed by a broadly construed UW claim 1. As UW claim 1, taken in light of the prior art, does not fairly teach or suggest Lilly's specifically claimed species, Lilly's claimed species are patentably distinct from a broadly construed UW

claim 1. As a patentably distinct species is a "separate patentable invention" from its dominating genus, there is no interference in fact between a broadly construed UW claim 1 and Lilly's corresponding claims.

Based on the facts presented, neither UW claim 1 nor UW claim 3 impedes the grant of Lilly's corresponding claims. Case, 730 F.2d at 750, 221 USPQ at 200. As UW's allegedly corresponding claims do not impede the issuance of Lilly's corresponding claims, there is no interference-in-fact. UW Preliminary Motion 1 for no interference-in-fact is ***granted***.

3. Lilly Did Not Have Authorization to Set Its Own Time Period for Filing Motions to Add or Substitute a Count

Lilly had a full and fair opportunity to file motions responding to UW's motion for no interference-in-fact. Specifically, UW's motion was filed under Rule 633(b). Rule 633(i) permits a party to respond to such a motion by filing a motion to: (i) redefine the interfering subject matter (633(c)); (ii) substitute a different application (633(d)); or (iii) add a reissue application to the interference (633(h)). As such, Lilly had the opportunity to file a motion to redefine the interfering subject matter by adding or substituting a count or seek to have the claim correspondence changed. See, 37 CFR §§ 1.633(b), (c) and (i). Rather than file a motion to add or substitute a count, Lilly stated that:

> If this interference proceeds, further redefinition of the interfering subject matter would be necessary and desirable. For example, some modification of the Count itself will be necessary under 37 C.F.R. § 1.633(c)(1) so that it encompasses the subject

> matter of the involved Bang reissue claims currently designated as corresponding to the count. Otherwise, Lilly could be improperly denied the opportunity to present its best priority proofs. [Citation omitted]. Such modification of the Count is not necessary to resolve the interference-in-fact issue that is the subject of this special motion period, which merely turns on the "same patentable invention" relationship between the respective claims of the parties designated as corresponding to the Count. If a Preliminary Motion Period is set, Lilly will present an appropriate motion to modify the Count itself to exercise its right to have a count representing its "best proofs." In the same vein, Lilly will move during the Preliminary Motions Period to appropriately further modify the scope of the interference by designating the appropriate claims of the parties as corresponding to the Count.

(Lilly Preliminary Motion 1, Paper No. 22, p. 6, fn. 2).

Under the rules, a preliminary motion under §§ 1.633 (a) through (h) shall be filed within a time period set by an APJ . Moreover, the time for filing motions under § 1.633 (i) is twenty (20) days after service of the initial motion under rule 633(a), (b), (c)(1) or (g), unless otherwise ordered by an APJ. 37 CFR §§ 1.636 (a) and (b).

In this case, an APJ set a specific time period for filing motions for no interference-in-fact or for judgment of unpatentability under 35 U.S.C. § 135(b). (Order, Paper No. 16). The APJ also set a specific time period for filing responsive rule 633(i) and 0) preliminary motions. (Order, Paper No. 16). As noted above, Lilly has chosen to *sua*

sponte set its own schedule for submitting motions to redefine the interfering subject matter.

Lilly's failure to comply with the times set by the APJ undermines the APJ's ability to secure a "just, speedy, and inexpensive" determination of this interference. By failing to timely file its motions to redefine the interfering subject matter, Lilly has avoided the difficult and complex question of what a proper count and claim correspondence would be if this interference were to proceed. Further, if Lilly had timely filed its "necessary and desirable" motions to redefine the interfering subject matter, Lilly's motions may have provided additional evidence regarding the existence of an interference-in-fact or lack thereof. Lilly instead chose a more limited approach and is subject to the consequences of its choices.

4. The Panel Will Not Exercise Its Discretion Under Rule 641 to Review the Patentability of UW Claim 1

Lilly has argued that the issue of UW's written descriptive support for UW claim 1 is presently before the Board. This is not the case. Neither Lilly nor UW has briefed this particular issue. Moreover, as the panel has determined that there is no interference-in-fact between UW and Lilly, no Rule 1.633(a) patentability motions will be accepted from the parties. This is not to say that the panel has determined that UW claim 1 is patentable, but rather it is a recognition that Lilly will not be afforded the opportunity to submit unpatentability motions where there is no interference-in-fact. *Berman v. Housey*, 2002 U.S. App. LEXIS 10256 at *24 (Fed. Cir. 2002)(Refusal by Board to address issues of priority and patentability once it determined that there is no

interference-in-fact is supported by sound policy considerations).

During the course of an interference, if an APJ become aware of a reason why a claim designated as corresponding to the count may not be patentable, the APJ has the discretion to enter an order notifying the parties of the reasons and set a time for each party to present its views. 37 CFR § 1.641. This interference was declared based, in part, on Lilly's allegations that a nucleotide sequence encoding protein C deposited by UW was identical to that of Lilly's. These allegations proved to be erroneous, albeit inadvertently. Given the circumstances of this interference, the panel chooses not to exercise its discretion under Rule 1.641 and explore the patentability or unpatentability of UW claim 1.

5. Lilly Contingent Miscellaneous Motion 2 is Moot

Lilly filed a motion seeking leave to belatedly file a preliminary statement. (Lilly Contingent Miscellaneous Motion 2, Paper No. 41, p. 1). Lilly's motion is contingent on the determination that there is an interference-in-fact. As we have granted UW Preliminary Motion 1 for no interference-in-fact, Lilly's miscellaneous motion is moot.

6. Additional Comments

Lilly has argued that they have no other remedy in the USPTO. (Paper No. 27, p. 11). According to Lilly, a reexamination of UW's 529 patent is not available as Lilly's `624 patent was cited during the prosecution of UW's patent and UW overcame this rejection by filing a declaration under 37 CFR § 1.131. As such, Lilly concludes that the issue of

Lilly's alleged work under § 102(g) should be resolved in an interference proceeding. Lilly also argues that the failure to recognize an interference-in-fact under the present circumstances leads to the "absurd, inequitable, and unlawful" result that Lilly's practice of its own prior invention may be alleged to infringe UW's claims.

The existence or nonexistence of another remedy within the USPTO is not a basis for continuing an interference where none exists. Should Lilly believe that an actual controversy exists between the UW `529 patent and Lilly's activities, Lilly may file a declaratory judgment action in district court.

ORDER

Upon consideration of the motions, it is:

ORDERED that UW Preliminary Motion 1 for no interference-in-fact is ***granted***.

FURTHER ORDERED that there is no interference-in-fact between claims 1 and 3 of UW, U.S. Patent No. 5,302,529 and claims 1-82 and 84-90 of Lilly, U.S. Application No. 09/185,663.

FURTHER ORDERED that Lilly Preliminary Motion 1 to designate an additional patent claim is ***moot***.

FURTHER ORDERED that Lilly Contingent Miscellaneous Motion 2 for leave to belatedly file a preliminary motion is ***moot***.

FURTHER ORDERED that if there is a settlement agreement, attention is directed to 35 U.S.C. § 135(c) and 37 CFR § 1.661.

FURTHER ORDERED that a copy of this final decision shall be placed and given a paper number in the file of Foster, U.S. Patent No. 5,302,529 and Bang, U.S. Application No. 09/185,663.

RICHARD E. SCHAFER
Administrative Patent Judge

RICHARD TORCZON
Administrative Patent Judge

MICHAEL P. TIERNEY
Administrative Patent Judge

BOARD OF PATENT APPEALS AND INTERFERENCES

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APPENDIX C

United States Court of Appeals for the Federal Circuit

02-1610
(Interference 104,746)

ELI LILLY & CO.

Appellant,

v.

BOARD OF REGENTS OF THE
UNIVERSITY OF WASHINGTON,

Appellee.

FILED
U.S. COURT OF
APPEALS FOR THE
FEDERAL CIRCUIT

Oct 15 2003

JAN HORBALY
CLERK

ORDER

ORDER

A combined petition for panel rehearing and for rehearing en banc having been filed by the APPELLANT*, and a response thereto having been invited by the court and filed by the APPELLEE, and the petition for rehearing having been referred to the panel that heard the appeal, and thereafter the petition for rehearing en banc and response having been referred to the circuit judges who are in regular active service,

UPON CONSIDERATION THEREOF, it is

ORDERED that the petition for panel rehearing be, and the same hereby is, DENIED and it is further

ORDERED that the petition for rehearing en banc be, and the same hereby is, DENIED.

The mandate of the court will issue on October 22, 2003.

NEWMAN, LOURIE, and RADER, Circuit Judges, would rehear the appeal.

FOR THE COURT,

s/ Jan Horbaly
Jan Horbaly
Clerk

Dated: October 15, 2003

cc: Charles E. Lipsey
Henry N. Wixon
John M. Whealan, Nancy J. Linck
Jeffrey P. Kushan, Charles L. Gholz

ELI LILLY V BD OF REGENTS, 02-1610
(PTO - 104, 733)
* Amici briefs were filed by: 1 - Guilford Pharmaceuticals, Inc. 2 - Genentech, Inc. 3- OBLON, SPIVAK, McCLELLAND, MAIER & NEUSTADT, P.C. and 4 - The Director of the United States Patent and Trademark Office.

****
*
* Note: Pursuant to Fed. Cir. R. 47.6, this order is not *
* citable as precedent. It is a public record. *
*
****

(2)

No. 03-1014

Supreme Court, U.S.
FILED
FEB 27 2004
OFFICE OF THE CLERK

In The

Supreme Court of the United States

ELI LILLY & CO.,

Petitioner,

v.

BOARD OF REGENTS OF THE UNIVERSITY OF WASHINGTON,

Respondent.

On Petition For Writ Of Certiorari To The United States Court Of Appeals For The Federal Circuit

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QUESTION PRESENTED

The United States patent laws provide that "[w]henever an application is made for a patent which, *in the opinion of the Director* [of the United States Patent and Trademark Office], would interfere with any pending application, or with any unexpired patent, an interference *may* be declared[.]" 35 U.S.C. § 135(a) (emphases added). The question presented is:

Whether the Patent and Trademark Office exceeded its discretion under 35 U.S.C. § 135(a) by refusing to conduct an interference between a "species" claim to a specific cDNA sequence coding for a particular human protein and a "genus" claim to the class of cDNA sequences coding for that protein on the grounds that under the agency's interference rules the species and genus claims were not directed to "the same patentable invention"?

PARTIES TO THE PROCEEDING BELOW

Eli Lilly & Company and the Board of Regents of the University of Washington were the parties to the proceedings below. ZymoGenetics, Inc., which licensed the patent at issue from the University of Washington, is a real party in interest. The Novo Group (including Novo Nordisk A/S and Novo A/S) owns 10 percent or more of the stock of ZymoGenetics.

TABLE OF CONTENTS

	Page
QUESTION PRESENTED	i
PARTIES TO THE PROCEEDING BELOW	ii
TABLE OF CONTENTS	iii
TABLE OF AUTHORITIES	v
CONSTITUTIONAL AND STATUTORY PROVISIONS	1
STATEMENT OF THE CASE	4
A. The Patent Statute Affords the Patent and Trademark Office Discretion to Conduct or Decline to Conduct Interferences	4
B. The Patent Office Simply Applied Its Rules in this Case	9
C. The Federal Circuit Properly Recognized the PTO's Discretion to Use a Two-Way Test Generally, and in this Particular Case	11
REASONS FOR DENYING THE WRIT	12
A. The Decision Below Is Consistent with the Plain Language of the Statute Governing Interferences, and with the Precedent of this Court and the Federal Circuit	12
1. The Plain Language of the Statute and Case Law Dictate Deference to the Discretion of the PTO	12
2. Section 135(a) Does Not Conflict with Other Provisions of the Patent Statute or with Prior Case Law	14
B. Judicial Interference with the PTO's Discretion Under 35 U.S.C. § 135(a) Would Have Adverse Consequences	17

TABLE OF CONTENTS – Continued

Page

1. The "One-Way Test" Would Do More Harm Than Good 17

2. Abrogating the PTO's Discretion to Conduct Interferences Could Impact PTO Rules Other Than 601(n) 21

C. The Unique Circumstances of Lilly's Case Do Not Implicate Matters of Widespread Public Importance to Intellectual Property Owners 22

CONCLUSION 25

TABLE OF AUTHORITIES

Page

FEDERAL CASES

Abrutyn v. Giovanniello, 15 F.3d 1048 (Fed. Cir. 1994) 13

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Auer v. Robbins, 519 U.S. 452 (1997) 11

Barton v. Adang, 162 F.3d 1140 (Fed. Cir. 1998) 13

Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc., 246 F.3d 1368 (Fed. Cir. 2001) 6, 16

Chiong v. Roland, 17 U.S.P.Q.2d 1541 (Bd. Pat. App. & Int. 1990) 7

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Eli Lilly & Co. v. Barr Labs., Inc., 251 F.3d 955 (Fed. Cir. 2001), *cert. denied*, 534 U.S. 1109 (2002) 21

Ewing v. United States ex Rel. The Fowler Car Co., 244 U.S. 1 (1917) 13, 17

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Hester v. Allgeier, 687 F.2d 464 (C.C.P.A. 1982) 7

MCI Telecomms. Corp. v. American Tel. and Tel. Co., 512 U.S. 218 (1994) 14

Morton v. Mancari, 417 U.S. 535 (1974) 14

United States v. Larionoff, 431 U.S. 864 (1977) 14

TABLE OF AUTHORITIES – Continued

Page

Utter v. Hiraga, 845 F.2d 993 (Fed. Cir. 1988) 7

Winter v. Fujita, 53 U.S.P.Q.2d 1234 (Bd. Pat. App. & Int. 1999) 6, 7

FEDERAL STATUTES

35 U.S.C. § 102 5

35 U.S.C. § 102(g) 9, 16

35 U.S.C. § 103 5

35 U.S.C. § 135 ..... 15, 17, 24

35 U.S.C. § 135(a) ..... *passim*

35 U.S.C. § 146 ..... 1, 16

35 U.S.C. § 282 ..... 1, 21

35 U.S.C. § 291 ..... 2, 16, 17

REGULATIONS

37 C.F.R. § 1.601 ..... 4, 5

37 C.F.R. § 1.601(j) 2, 4, 5

37 C.F.R. § 1.601(m) 2, 21

37 C.F.R. § 1.601(n) ..... *passim*

37 C.F.R. § 1.602 ..... 3, 21

37 C.F.R. § 1.608 3

37 C.F.R. § 1.608(a) 22

37 C.F.R. § 1.608(b) 22

TABLE OF AUTHORITIES – Continued

Page

OTHER

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Comment of William P. Berridge on 0651-AB29: Standard for Declaring a Patent Interference (February 26, 2001), *at* http://www.uspto.gov/web/offices/dcom/bpai/rule/wberridge.htm 18

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To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy, 2003 WL 22507757 (F.T.C. October, 2003) 23, 24

CONSTITUTIONAL AND STATUTORY PROVISIONS

35 U.S.C. § 146 (in relevant part)

> Civil action in case of interference
>
> Any party to an interference dissatisfied with the decision of the Board of Patent Appeals and Interferences on the interference, may have remedy by civil action, if commenced within such time after such decision, not less than sixty days, as the Director appoints or as provided in section 141 of this title, unless he has appealed to the United States Court of Appeals for the Federal Circuit, and such appeal is pending or has been decided. In such suits the record in the Patent and Trademark Office shall be admitted on motion of either party upon the terms and conditions as to costs, expenses, and the further cross-examination of the witnesses as the court imposes, without prejudice to the right of the parties to take further testimony. The testimony and exhibits of the record in the Patent and Trademark Office when admitted shall have the same effect as if originally taken and produced in the suit.

35 U.S.C. § 282 (in relevant part)

> Presumption of validity; defenses
>
> A patent shall be presumed valid. Each claim of a patent (whether in independent, dependent, or multiple dependent form) shall be presumed valid independently of the validity of other claims; dependent or multiple dependent claims shall be presumed valid even though dependent upon an invalid claim.

35 U.S.C. § 291

Interfering Patents

The owner of an interfering patent may have relief against the owner of another by civil action, and the court may adjudge the question of the validity of any of the interfering patents, in whole or in part. The provisions of the second paragraph of section 146 of this title shall apply to actions brought under this section.

37 C.F.R. § 1.601(j)

Scope of Rules, Definitions

(j) An *interference-in-fact* exists when at least one claim of a party that is designated to correspond to a count and at least one claim of an opponent that is designated to correspond to the count define the same patentable invention.

37 C.F.R. § 1.601(m)

Scope of Rules, Definitions

(m) A *senior party* is the party with the earliest effective filing date as to all counts or, if there is no party with the earliest effective filing date as to all counts, the party with the earliest filing date. A *junior party* is any other party.

37 C.F.R. § 1.601(n)

Scope of Rules, Definitions

(n) Invention "A" is the *same patentable invention* as an invention "B" when invention "A" is the same as (35 U.S.C. 102) or is obvious (35 U.S.C. 103) in view of invention "B" assuming invention "B" is prior art with respect to invention "A". Invention "A" is a *separate patentable*

invention with respect to invention "B" when invention "A" is new (35 U.S.C. 102) and nonobvious (35 U.S.C. 103) in view of invention "B" assuming invention "B" is prior art with respect to invention "A".

37 C.F.R. § 1.602 (in relevant part)

Interest in applications and patents involved in an interference

(a) Unless good cause is shown, an interference shall not be declared or continued between (1) applications owned by a single party or (2) applications and an unexpired patent owned by a single party.

37 C.F.R. § 1.608 (in relevant part)

Interference between an application and a patent; *prima facie* showing by applicant

(a) When the effective filing date of an application is three months or less after the effective filing date of a patent, before an interference will be declared, either the applicant or the applicant's attorney or agent of record shall file a statement alleging that there is a basis upon which the applicant is entitled to a judgment relative to the patentee.

(b) When the effective filing date of an application is more than three months after the effective filing date of a patent, the applicant, before an interference will be declared, shall file evidence which may consist of patents or printed publications, other documents, and one or more affidavits which demonstrate that applicant is *prima facie* entitled to a judgment relative to the patentee and an explanation stating with particularity the

> basis upon which the applicant is *prima facie* entitled to the judgment. . . . If an examiner finds an application to be in condition for declaration of an interference, the examiner will consider the evidence and explanation only to the extent of determining whether a basis upon which the application would be entitled to a judgment relative to the patentee is alleged and, if a basis is alleged, an interference may be declared.

STATEMENT OF THE CASE

The United States Patent and Trademark Office ("PTO") has discretion to conduct patent interference proceedings pursuant to 35 U.S.C. § 135(a). In accordance with that statutory authority, the PTO has promulgated rules to govern the conduct of interference proceedings, *see* 37 C.F.R. §§ 1.601-1.690, including a rule providing that interferences will only be conducted between patent claims directed to the "same patentable invention." 37 C.F.R. § 1.601(j).

In this case the PTO did nothing more than apply its own interference rules to conclude that certain patent claims of Petitioner Eli Lilly & Company ("Lilly") and Respondent Board of Regents of the University of Washington ("UW") were not directed to the same patentable invention, and therefore not properly the subject of an interference proceeding.

A. The Patent Statute Affords the Patent and Trademark Office Discretion to Conduct or Decline to Conduct Interferences

The United States patent laws permit the PTO to determine whether two patent applications (or a patent

application and an issued patent) are drawn to the "same patentable invention" and, if so, to conduct an interference proceeding to decide priority of invention, *i.e.*, who was first to invent the claimed subject matter and is therefore entitled to the patent. *See Conservolite, Inc. v. Widmayer*, 21 F.3d 1098, 1100-01 (Fed. Cir. 1994), *cert. denied*, 513 U.S. 1016 (1994). The statute governing interference proceedings before the PTO makes clear that declaration of an interference is discretionary, stating in pertinent part that "[w]henever an application is made for a patent which, *in the opinion of the Director*, would interfere with . . . any unexpired patent, an interference *may* be declared[.]" 35 U.S.C. § 135(a) (emphases added).

Pursuant to 35 U.S.C. § 135(a), the PTO has enacted various regulations governing the declaration and conduct of interference proceedings. *See, e.g.*, 37 C.F.R. §§ 1.601-1.690. One of the rules provides that the PTO will only conduct an interference when patent claims are directed to the "same patentable invention." 37 C.F.R. § 1.601(j). The PTO rules define "same" and "separate" patentable inventions as follows:

> Invention "A" is the *same patentable invention* as an invention "B" when invention "A" is the same as (35 U.S.C. [§] 102) or is obvious (35 U.S.C. [§] 103) in view of invention "B" assuming invention "B" is prior art with respect to invention "A." Invention "A" is a *separate patentable invention* with respect to invention "B" when invention "A" is new (35 U.S.C. [§] 102) and non-obvious (35 U.S.C. [§] 103) in view of invention "B" assuming invention "B" is prior art with respect to invention "A."

37 C.F.R. § 1.601(n).

When Rule 601(n) was adopted in 1984 as part of a major overhaul of the PTO's regulations, the agency explicitly addressed the issue of whether genus and species claims define "same" or "separate" patentable inventions.[1] The PTO concluded that "if a species is patentable over a genus, the species is a 'separate patentable invention' from the genus."[2] 49 Fed. Reg. 48,416, 48,433 (Dec. 12, 1984).

Approximately fifteen years later, in *Winter v. Fujita*, 53 U.S.P.Q.2d 1234, 1243 (Bd. Pat. App. & Int. 1999), the Board of Patent Appeals and Interferences further clarified the PTO regulations governing "same" and "separate" patentable inventions, clearly stating that it would apply a so-called "two-way" patentability analysis in deciding whether to declare an interference between patent claims. In a case involving priority between inventions A and B, the "two-way" test requires that Invention A anticipates or renders obvious Invention B *and* Invention B anticipates or renders obvious Invention A in order for an interference to be declared. *See id.* The explicit adoption of the two-way test effectively maintained the agency's prior position that no interference would be declared between genus and

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[1] "Genus" claims are directed to a class, such as UW's claim to cDNA sequences coding for a particular human protein. In contrast, "species" claims are directed to a specific subpart of the genus, such as Lilly's claims to a specific cDNA sequence coding for that protein.

[2] *See, e.g., Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc.*, 246 F.3d 1368, 1380 (Fed. Cir. 2001).

species claims, so long as the species was patentable over the genus.[3]

In adopting the "two-way" test, the PTO rejected a more inclusive "one-way" test, which would result in an interference if Invention A anticipated or rendered obvious Invention B *or* Invention B anticipated or rendered obvious Invention A. The one-way test would, therefore, always result in interferences between genus and species claims, even if the species (as is often the case) was ultimately found to be later invented and patentable over the genus. The PTO's adoption of the more restrictive two-way test effectively ensured that interferences would only be conducted in circumstances where there was no possibility of two patentable inventions.

After the *Winter* decision, the PTO requested public comment on whether to abandon the two-way patentability test and adopt the more inclusive one-way test. *See* 65 Fed. Reg. 79,809, 79,809-10 (Dec. 20, 2000). In soliciting the comments, the PTO articulated serious concerns with

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[3] Lilly's assertion that the two-way test is "not long-standing" (Pet. at 22) is incorrect. Prior to and after the adoption of Rule 601(n), the PTO took the position that genus and species could be patentably distinct. *See, e.g., Hester v. Allgeier,* 687 F.2d 464, 465-67 (C.C.P.A. 1982) (affirming the Board's holding that a count to a genus and a count to a species within the genus were patentably distinct); *Utter v. Hiraga*, 845 F.2d 993, 998 (Fed. Cir. 1988) ("There is no inconsistency in awarding a generic count to one inventor, while awarding a patentably distinct species count to another, however."); *Chiong v. Roland,* 17 U.S.P.Q.2d 1541, 1544 (Bd. Pat. App. & Int. 1990) (citing the 1984 Notice of Final Rules as pointing out that "the standard of patentability will not be applied 'on a mutual basis'" and stating "[i]f a species claim is patentable over a generic claim, the species claim is a separate patentable invention from the generic claim.")

adopting the expansive one-way test for which petitioner now advocates. *See id.* Significantly, the PTO noted the strain on resources and other problems that adoption of a one-way test would cause:

> Any decision to expand the nature of interference proceedings will have a resource consequence for USPTO and for applicants and patentees involved in interferences. Approximately one-quarter of the resources of the Board of Patent Appeals and Interferences are used to resolve interferences, notwithstanding the fact that there are many more appeals than interferences. USPTO has received many reports that interferences involve considerable costs for applicants and patentees. Additionally, there is no desire on the part of USPTO, and no authority under the law, to turn interference proceedings under 35 U.S.C. [§] 135(a) into pre-grant oppositions or post-grant cancellations. Accordingly, USPTO is reluctant, at this time, to expand the circumstances under which an interference might be declared or maintained absent a compelling reason.

Id. at 79,810. Ultimately, after reviewing the comments, the PTO reiterated its intention to retain the two-way patentability test. *See* Board of Patent Appeals and Interferences, Answers to Frequently Asked Questions (June 7, 2001), at pp. 5-6, *at* www.uspto.gov/web/offices/dcom/bpai/bpaifaq.htm.

More recently, the PTO has published notice of its intention to amend its rules to make even more clear that

the two-way test applies.[4] *See* 68 Fed. Reg. 66,648, 66,664-65 (Nov. 26, 2003). In its notice of the proposed rule, the PTO has stated that "[t]he Director uses a two-way unpatentability test to determine whether claimed inventions interfere because, while a one-way test is only sufficient for rejecting a claim under 35 U.S.C. [§] 102(g), a two-way test is necessary to ensure that the claims of both parties are directed to the same invention." *Id.*

B. The Patent Office Simply Applied Its Rules in this Case

In November 1998, Lilly filed a reissue patent application for the purpose of provoking an interference proceeding with three issued patents assigned to UW, including United States Patent No. 5,302,529 (the "Foster patent"). Lilly's reissue application included species claims to a specific cDNA sequence coding for human protein C, which plays an important role in the regulation of blood coagulation. UW's Foster patent included not only species claims to a specific cDNA sequence coding for human protein C, but also a broader genus claim to the class of nucleotide sequences coding for human protein C.

In order to provoke an interference between the Lilly reissue application and UW's Foster patent, Lilly repeatedly (and incorrectly) told the PTO that its reissue application and the Foster patent included claims to identical

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[4] Proposed rule 37 C.F.R. § 41.203(a) would clarify that an "interference exists if the subject matter of a claim of one party would, if prior art, have anticipated or rendered obvious the subject matter of a claim of the opposing party and vice versa." 68 Fed. Reg. 66,648, 66,689 (Nov. 26, 2003).

cDNA sequences, and thereby included claims to the "same patentable invention." Based on Lilly's erroneous assertions, the PTO declared an interference proceeding between the respective species claims of Lilly's reissue application and the Foster patent. Only after UW sought to have the PTO declare that no interference existed did Lilly admit that its assertions had been wrong, and that the cDNA sequences of the claims involved in the interference were different.

Lilly then urged the PTO not to terminate the interference on the grounds that Lilly's species claims and UW's genus claim[5] to the class of cDNA sequences coding for human protein C were directed to the "same patentable invention." The PTO, applying its regulations, held that UW's genus claim (construed broadly) and Lilly's species claims were "separate patentable inventions" because Lilly's species claims were patentable over UW's genus claim.[6] As a consequence, the PTO refused to conduct an interference proceeding to determine priority of inventorship between the species claims in Lilly's reissue application and the genus claim in the Foster patent.

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[5] Based on Lilly's factual misrepresentations, the PTO had not included UW's genus claim in declaring the interference. During the proceedings before the PTO, Lilly declined actually to admit that UW's genus claim did, in fact, cover Lilly's claimed species. Instead, Lilly proposed alternative claim constructions for the claim (a broad genus or a narrow species) and asked the PTO to make a choice. The PTO declined to do so, but did thoroughly analyze both constructions in concluding that there was no interference in fact.

[6] Given that the PTO explicitly considered the issue of whether to continue the interference between UW's genus claim and Lilly's species claims, the assertion in Lilly's petition that the "Board did not choose to consider UW's genus claim" (Pet. at 5) is incorrect.

C. The Federal Circuit Properly Recognized the PTO's Discretion to Use a Two-Way Test Generally, and in this Particular Case

Lilly appealed the PTO's decision to the Federal Circuit, which affirmed the agency determination. That court held that the declaration of an interference is discretionary, according to the plain meaning of 35 U.S.C. § 135. In addition, based on the submission of an amicus brief by the Director of the PTO, the Federal Circuit found that the PTO interprets its own Rule 601(n), defining "same" and "separate" patentable inventions, as requiring a "two-way" test. Finally, the Federal Circuit held that the PTO's application of a "two-way" test under its own regulations was a permissible exercise of the agency's discretion under Section 135(a).[7]

In deciding that the PTO had not exceeded its discretion, the Federal Circuit explicitly noted that the PTO's adoption of a two-way test was not plainly erroneous or inconsistent with the PTO's regulations. The Federal Circuit also observed that, as a policy matter, the two-way test avoids the proliferation of unnecessary, wasteful interference proceedings in situations where the claimed inventions do not define the same patentable invention, but merely overlap in scope. In the specific context of

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[7] Lilly incorrectly asserts that the Federal Circuit construed Section 135(a) "to mean that the PTO has complete, unrestrained discretion to interpret its rules as it chooses." (Pet. at 7.) In fact, the court below simply stated that the PTO's interpretation of its own regulations "is controlling unless 'plainly erroneous or inconsistent with the regulation.'" (Pet. App. 11, *citing Auer v. Robbins*, 519 U.S. 452, 461 (1997)). The Federal Circuit further concluded that the PTO's use of a two-way test "easily met" the deferential standard. (Pet. App. 12.)

genus and species claims, the two-way test ensures that the PTO does not conduct a lengthy and costly interference proceeding only to conclude that a later invented species is separately patentable over an earlier invented genus.

Lilly requested a rehearing by the Federal Circuit sitting *en banc*. In connection with the petition for rehearing, only four amicus briefs were submitted. Of the three in favor of the one-way test, two were filed by or on behalf of a law firm that, by its own account, handles more interferences than any other law firm in the country. The Director of the PTO submitted the only other amicus brief, stating that 35 U.S.C. § 135(a) "makes abundantly clear that the Director has discretion to determine the type of test used for interference proceedings" and that the "two-way test is consistent with the patent laws." (PTO Amicus Brief filed September 9, 2003 at 1-2.)

The Federal Circuit denied the request for rehearing.

REASONS FOR DENYING THE WRIT

A. The Decision Below is Consistent with the Plain Language of the Statute Governing Interferences, and with the Precedent of this Court and the Federal Circuit

1. The Plain Language of the Statute and Case Law Dictate Deference to the Discretion of the PTO

The Federal Circuit properly recognized that declaration of an interference by the PTO is discretionary pursuant to 35 U.S.C. § 135(a), which states that an interference "*may*" be declared if "*in the opinion of the Director*" it

appears that two parties are claiming the same invention. (Pet. App. 8.) That court also correctly held that the PTO's use of a two-way test under 37 C.F.R. 1.601(n) to determine whether claims are directed to the "same patentable invention" constitutes "the clear application of discretion that is inherent in the authority granted pursuant to 35 U.S.C. § 135(a)[.]" (Pet. App. 11.)

Hardly a departure from controlling case law, the Federal Circuit's decision is consistent with longstanding precedent from this Court. In *Ewing v. United States ex Rel. The Fowler Car Co.*, 244 U.S. 1, 10 (1917), the Court held that the language "in the opinion of the Commissioner" in the predecessor statute to Section 135(a) gave the Commissioner of Patents discretion to decline to proceed with an interference proceeding.[8] The decision below is also consistent with Federal Circuit precedent holding that "[t]he plain meaning of [35 U.S.C. § 135(a)] is clear from the use of the permissive term 'may' that the [Director] has discretion whether to declare an interference." *Barton v. Adang*, 162 F.3d 1140, 1144 (Fed. Cir. 1998). *See also Abrutyn v. Giovanniello*, 15 F.3d 1048, 1050 (Fed. Cir. 1994) (the Federal Circuit reviews a Board decision pursuant to the permissive rules governing a patent interference proceeding for abuse of discretion.)

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[8] Lilly attempts to diminish the importance of the precedent set by *Ewing* on the grounds that it involved different facts. (Pet. at 19.) *Ewing*, however, clearly recognized the broad discretion of the PTO to declare interferences. Furthermore, the *Ewing* Court gave no indication that its statements regarding the PTO's discretion were confined to the particular facts of that case.

2. Section 135(a) Does Not Conflict with Other Provisions of the Patent Statute or with Prior Case Law

Notwithstanding the clear congressional intent under 35 U.S.C. § 135(a) to grant the PTO discretion to conduct interferences, Lilly asserts that Rule 601(n), as interpreted by the PTO, is contrary to the "Patent Statute" and a body of case law generally stating that "only one patent should issue for inventions which are either identical to or not patentably distinct from each other." (Pet. at 10.) Lilly's claim of a "conflict" is erroneous for at least three reasons.

First, nothing in any provision of Title 35 cited by Lilly explicitly or implicitly limits the permissive language of Section 135(a) – the only provision in the Patent Statute that addresses interferences. *See Morton v. Mancari*, 417 U.S. 535, 550-51 (1974) (enforcing "specific provision, applying to a very specific situation" and noting that "courts are not at liberty to pick and choose among congressional enactments, and when two statutes are capable of co-existence, it is the duty of the courts, absent a clearly expressed congressional intention to the contrary, to regard each as effective"). Lilly provides no basis upon which the Court would be permitted to ignore the plain language of 135(a) in favor of other provisions in the Patent Statute that do not even mention interferences.[9]

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[9] Lilly's citations (Pet. at 12) to cases in which this Court has found that agencies exceeded their statutory authority are inapplicable here. For example, *MCI Telecomms. Corp. v. American Tel. and Tel. Co.*, 512 U.S. 218, 225 (1994), simply involved the correct interpretation of the word "modify" in a statute. Similarly, *United States v. Larionoff*, 431

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Second, the cases and statutes Lilly cites to support its claim of a "conflict" (Pet. at 10) do not demonstrate a conflict at all. For example, in *Aelony v. Arni*, the Federal Circuit's predecessor held that the "test of interference in fact is not whether two sets of claims overlap, but whether they are patentably distinct from *each other*." 547 F.2d 566, 570 (C.C.P.A. 1977) (emphasis added). *Aelony's* holding hardly conflicts with the two-way test, and was actually cited by the PTO to support its dismissal of the interference at issue here.

Other cases Lilly cites say nothing about the correct standard for the declaration of interferences in the PTO, and simply stand for the general proposition that only one patent should issue for one invention. *See, e.g., Apotex USA, Inc. v. Merck & Co., Inc.*, 254 F.3d 1031, 1035 (Fed. Cir. 2001), *cert. denied*, 534 U.S. 1172 (2002). Lilly's assertion that the PTO's two-way test conflicts with these cases rests upon the false premise that its species claim and UW's genus claim are necessarily directed to the "same patentable invention." That premise is not true here and it is not true in many cases involving genus and species claims. As the PTO and the Federal Circuit have both stated, species and genus claims are not always directed to the same patentable invention. A later species claim can be patentably distinct from an earlier genus

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U.S. 864, 873 (1977), merely expressed the uncontroversial proposition that agency regulations must be consistent with the statutory authority pursuant to which they are promulgated. In this case, the grant of discretion to the PTO in 35 U.S.C. § 135 is clear and unambiguous, and requires no statutory construction.

claim.[10] *See Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc.*, 246 F.3d 1368, 1380 (Fed. Cir. 2001). Thus, the use of a two-way test simply ensures that interferences will not be conducted in cases where one possible outcome is two patentable inventions – one to a genus and one to a species.

Finally, the mere possibility that UW's genus claim and Lilly's species claim are not separately patentable, does not require that the PTO make a priority determination. Pursuant to Title 35, the PTO and the federal courts share responsibility for addressing patentability issues, including priority of invention under 35 U.S.C. § 102(g). In addition to the PTO interference proceedings provided in Section 135, patentees have the option to pursue interference proceedings in the federal courts under 35 U.S.C. §§ 291 and 146. Furthermore, in the event of an actual case or controversy involving the Lilly or UW patents (such as a patent infringement lawsuit), the federal courts will have jurisdiction to address the priority issue.

Thus, while Lilly may believe, as a policy matter, that priority issues are best resolved in administrative proceedings before the PTO rather than in the courts, nothing in Title 35 dictates such a conclusion. Indeed, this Court long ago rejected such an argument, noting that the judicial remedy provided by the predecessor to 35 U.S.C. § 291 adequately addressed any potential loss of rights caused

[10] For example, in this case an interference could result in the conclusion that UW's genus claim was first, and Lilly's species claim was second but nevertheless patentable over UW's genus claim. The two claims could thus coexist as separate patentable inventions, and the interference would have been unnecessary.

by the PTO's failure to proceed with an interference proceeding under the predecessor to 35 U.S.C. § 135. *See Ewing*, 244 U.S. at 10 (describing party's right to seek a judicial remedy under the predecessor statute to 35 U.S.C. § 291 and noting that "there is no defeat of ultimate rights; there may be *postponement* of their assertion remitted to a suit in equity[.]") (emphasis added).

In sum, the "statutory scheme" articulated in 35 U.S.C. § 135(a) clearly grants the PTO discretion to declare interferences, and the PTO's use of a "two-way" test falls well within the bounds of that discretion.

B. Judicial Interference with the PTO's Discretion Under 35 U.S.C. § 135(a) Would Have Adverse Consequences

Even if one were to accept the assertion (contrary to the plain language of 35 U.S.C. § 135 and the case law) that declaration of interference proceedings is not discretionary with the PTO, ordering the PTO to use a one-way test in determining whether to conduct interferences would cause more harm than good, and would cast uncertainty upon other interference rules involving agency discretion.

1. The "One-Way Test" Would Do More Harm Than Good

As has been noted by both the PTO and the Federal Circuit in its decision below, the one-way test advocated by Lilly would require the PTO to conduct interference proceedings in many priority contests involving patents and patent applications with broad and narrow claims. For example, the one-way test would include all instances in

which two pending applications (or a pending application and an issued patent) included genus-species claims, combination-subcombination claims, or improvement-subimprovement claims. In so doing, the one-way test would drag into interference practice many disputes in which an interference would ultimately be found not to exist (*e.g.*, in all cases involving later-filed, but patentably distinct species claims). The over-inclusive one-way test would thus result in unnecessary costs to the parties involved in interference proceedings as well as to the PTO. In addition, use of the one-way test would permit parties to provoke interference proceedings between pending applications or between issued patents (as was the case with Lilly here) by filing reissue applications and drawing issued patents into further protracted proceedings before the PTO.

When the PTO solicited comments on the one-way test, these concerns were raised:

> Converting to a one-way test would mean that improvement patents could always be in interference with the broader patents on which they improve, patents containing combination claims could always be in interference with patents containing broader subcombinations, patents containing species claims could always be in interference with patents containing broader genus claims, etc.

Comment of William P. Berridge on 0651-AB29: Standard for Declaring a Patent Interference (February 26, 2001), *at* http://www.uspto.gov/web/offices/dcom/bpai/rule/wberridge.htm. Other commentators have remarked upon the frustration of patentees (such as UW) who find themselves

dragged into protracted interference proceedings in the PTO:

> Once applicants survive [the application] process and successfully win the prize of being issued a patent, it is unsettling for the patentee to be put to the test yet again, especially in an interference context with a potentially aggressive and relentless opponent. Subjecting a patentee to unnecessary further scrutiny is also contrary to the primary function of the PTO.

Comment of Edward Kenehan on 0651-AB29: Standard for Declaring a Patent Interference *at* http://www.uspto.gov/web/offices/dcom/bpai/rule/ekenehan.htm. Indeed, in affirming its decision to follow the two-way test, the PTO noted the strain on resources and other changes that use of a one-way test would cause. *See* 65 Fed. Reg. 79,809, 79,810 (Dec. 20, 2000).

The Federal Circuit also noted the difficulty posed by species and genus claims.[11] The two-way test may be under-inclusive, insofar as it may not result in an interference between a presumptively prior species claim and a later genus claim. On the other hand, the one-way test advocated by Lilly would be over-inclusive, and result in declaration of interference proceedings between presumptively prior genus claims and later species claims. The

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[11] Lilly's assertion that the Federal Circuit acknowledged the "evils" of the two-way test is overstated, particularly with regard to its repeated use of the word "evil" to describe the administrative rule at issue. (Pet. at 8.) In fact, the Federal Circuit simply acknowledged the competing policy considerations motivating the PTO's adoption of the two-way test. (Pet. App. 14.)

Federal Circuit properly concluded that the PTO's choice of the under-inclusive two-way test rather than an over-inclusive one-way test constituted a permissible exercise of the agency's discretion under 35 U.S.C. § 135(a).

Lilly's attacks on the PTO for even considering efficiency and the proper allocation of resources in adopting the two-way test are unwarranted. For example, Lilly states "it defies logic" that the PTO has declined to conduct certain interferences on the grounds that it "wants to save money." (Pet. at 21.) Notwithstanding Lilly's strident tone, government agencies such as the PTO are often required to make difficult decisions concerning resource allocation. Indeed, Lilly's argument, taken to the extreme, would require the PTO to take every possible step, with no regard to "saving money," to ensure against the issuance of invalid patents. For example, in addition to requiring the PTO to conduct interference proceedings in all cases involving genus and species claims, such steps could require that patent examiners take on far fewer cases, conduct their own factual investigations for prior sales of the claimed invention, or conduct their own experiments (in a PTO laboratory built and equipped for that purpose) to independently verify the accuracy or reliability of a patent applicants' assertions. These are all costly actions that could diminish the chances of an invalid patent issuing, but would also jeopardize the fair and efficient operation of the agency. In sum, Lilly's contention that decisions be made without regard to resources is neither realistic nor supported by the statutory scheme. The PTO, which has a broad perspective and experience, is better able than the courts to allocate its own resources, and has properly done so here.

2. Abrogating the PTO's Discretion to Conduct Interferences Could Impact PTO Rules Other Than 601(n)

Rule 601(n) is not the only PTO rule that limits the type of cases in which the PTO will conduct interference proceedings.[12] Other rules exclude from interference practice situations that could possibly result in the PTO's issuance of two patents, one of which is presumptively invalid. (Pet. at 11.) For example, pursuant to 37 C.F.R. § 1.602, the PTO will not declare or continue an interference between applications (or between an application and an unexpired patent) owned by a single party, unless good cause is shown. Thus, in cases where one assignee obtains a patent on a genus claim and later seeks to obtain a patent on the species, no interference is declared absent good cause. If the PTO was required to conduct interferences in such cases, the number of interferences would greatly increase.[13]

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[12] Indeed, PTO administrative rules designed to streamline interference proceedings have been cited repeatedly and incorrectly by Lilly to attack UW's patent as "presumptively" invalid. *See, e.g.,* Pet. at 11. Under the interference rules, for ease of administration, Lilly is deemed the "Senior Party" solely upon the basis of the application date to which it claims priority. *See* 37 C.F.R. § 1.601(m). UW's issued U.S. patent is presumptively valid. *See* 35 U.S.C. § 282. Lilly's reissue application, by contrast, is entitled to no presumption of validity.

[13] Indeed, certain of the cases Lilly cites to support its assertion that the two-way test "conflicts" with existing Federal Circuit precedent involve situations in which a common assignee has both genus and species claims. *See, e.g.,* Pet. at 13 (*citing Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955 (Fed. Cir. 2001) and *Geneva Pharm., Inc. v. GlaxoSmithKline P.L.C.*, 349 F.3d 1373 (Fed. Cir. 2003). These cases do not "conflict" with PTO interference rules, insofar as the cases say nothing about whether priority determinations should be made in interference

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Similarly, pursuant to 37 C.F.R. § 1.608(b), an interference will not be declared if the effective filing date of an application is more than three months after the effective filing date of the allegedly interfering patent, absent evidence demonstrating that the applicant is *prima facie* entitled to a judgment relative to the patentee. If such evidence is presented, an interference "may" be declared. 37 C.F.R. § 1.608(b). Even if the effective filing date of the application is less than three months after the effective filing date of the patent, the applicant or the applicant's attorney still needs to file a statement alleging that there is a basis upon which the applicant is entitled to judgment relative to the patentee. *See* 37 C.F.R. § 1.608(a). Thus, the PTO regulations serve to limit interferences to situations in which there is a *bona fide* priority contest with some likely impact.

C. The Unique Circumstances of Lilly's Case Do Not Implicate Matters of Widespread Public Importance to Intellectual Property Owners

Lilly's precise complaint concerns a particularly unique situation in which the PTO declined to conduct an interference between a presumptive senior party (Lilly) with a species claim and a presumptive junior party (UW) with a genus claim. Any assertion that this precise factual circumstance is commonplace would be startling, insofar as it has taken nearly twenty years since the PTO rules

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proceedings before the PTO (rather than by federal courts). If anything, the cases cited by Lilly demonstrate that under the Patent Statute priority matters are capable of being addressed by the courts if and when they arise in the context of an actual patent dispute.

were promulgated in 1984 for this factual scenario even to reach the Federal Circuit. Thus, while this case is important to Lilly because it involves a patent covering Xigris®, one of Lilly's products, the precise facts would not appear to be routine.

Furthermore, even if this particular situation were replicated, the alleged harms of the PTO's two-way test referenced by Lilly are speculative, at best. Indeed, the only harm articulated is the possibility of "the public" or Lilly being subjected to a patent infringement suit by UW. Notably, no member of the "public" has raised such an issue. More importantly, however, if such a dispute were to arise, the federal courts would have jurisdiction to determine whether UW's patent was enforceable. Requiring Lilly to wait to adjudicate the validity of UW's patent until such time as an actual case or controversy exists is entirely consistent with the Patent Statute.

In order to bolster its contention that the patent system "as a whole" is harmed by the PTO's use of the two-way test, Lilly cites extensively to a recent report of the Federal Trade Commission ("FTC") entitled *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy*, 2003 WL 22507757 (F.T.C. October, 2003), in which the FTC discussed the harms caused by the issuance of invalid patents. (Pet. at 15-17.) The FTC report, however, says nothing about abandoning the two-way test or altering the conduct of interference proceedings.[14] Furthermore, the FTC report (unlike Lilly) clearly

[14] In the report, the FTC explicitly stated its intention to file amicus briefs in "important patent cases" with "high stakes for the

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acknowledges that certain of its proposed changes to the patent system must be accomplished by legislative amendment. For example, in its report, the FTC has proposed introducing an administrative procedure pursuant to which parties can challenge the validity of a patent in a proceeding before the PTO, without having to wait for federal court litigation, as is currently the case. *See id.* at *7 (Executive Summary, pp. 7-8). However, given that the Patent Statute does not currently give the PTO jurisdiction to conduct such post-grant opposition proceedings[15] (a distinction between the United States patent system and certain systems abroad), the FTC recognized that any post-grant review and opposition must be accomplished through authorizing legislation. Finally (and importantly), the FTC report (unlike Lilly) explicitly acknowledged the serious resource shortages at the PTO, noting the unanimous view that "the PTO does not receive sufficient funding for its responsibilities." *Id.* at *8 (Executive Summary, p. 10). The FTC report does not, therefore, provide any support for the proposition that the Court abrogate the explicit discretion of 35 U.S.C. § 135(a) to impose a one-way test on the PTO.

public." *Id.* at *14 (Executive Summary, p. 17). The FTC did not file an amicus brief in the proceedings below.

[15] As was noted in an amicus brief submitted by the PTO in response to Lilly's appeal to the Federal Circuit, the agency's "authority does *not* extend to provide an alternative avenue for third parties to attempt patent correction or cancellation under § 135." (PTO Amicus Brief filed February 4, 2003 at 22; emphasis in original.)

CONCLUSION

Lilly's petition for a writ of certiorari should be denied. The Federal Circuit properly held that the PTO's use of a "two-way" test generally, as well as in connection with the particular facts of this case, constituted an appropriate exercise of the agency's discretion under 35 U.S.C. § 135(a).

Respectfully submitted,

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Supreme Court, U.S.
FILED
MAR 8 - 2004
OFFICE OF THE CLERK

(3)

No. 03-1014

IN THE
Supreme Court of the United States

ELI LILLY & CO.,

Petitioner,

v.

BOARD OF REGENTS OF THE
UNIVERSITY OF WASHINGTON,

Respondent.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

PETITIONER'S REPLY BRIEF

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March 8, 2004

PARTIES TO THE PROCEEDING-BELOW

Eli Lilly & Company and the Board of Regents of the University of Washington were the parties to the proceedings below.

There are no corporations or publicly held companies that own 10 percent or more of the stock of Eli Lilly & Company and Eli Lilly & Company has no parent corporation.

TABLE OF CONTENTS

Page

PARTIES TO THE PROCEEDING BELOW i

TABLE OF CONTENTS ii

TABLE OF AUTHORITIES iii

I. Introduction 1

II. Argument 1

A. There Is an Overwhelming Public Interest that the PTO Hold an Interference So That Only One Valid Patent Is Issued for One Invention. 1

B. UW Has Never Defended Its Genus Claim or Explained How It Is Patentable Under the Patent Statute, But Instead Justifies the Federal Circuit's Decision Based on the PTO's Discretion 3

C. Despite UW's Use of Discretion as a Shield, the PTO Does Not Have Unlimited Discretion, But Must Abide by the Patent Statute as a Whole 6

CONCLUSION 7

TABLE OF AUTHORITIES

Chiong v. Roland,
17 U.S.P.Q.2d 1541 (Bd. Pat. App. & Int. 1990)..... 5

Hester v. Allgeier,
687 F.2d 464 (C.C.P.A. 1982) 5

Lamont v. Berguer,
7 U.S.P.Q.2d 1580 (Bd. Pat. App. & Int. 1988)..... 3

MCI Telecomm. Corp. v. American Tel. and Tel. Co.,
512 U.S. 218 (1994)..... 6

Public Citizen v. Nuclear Regulatory Commission,
901 F.2d 147 (D.C. Cir. 1990) 6

In re Slayter,
276 F.2d 408 (C.C.P.A. 1960) 3

Titanium Metals Corp. of America v. Banner,
778 F.2d 775 (Fed. Cir. 1985)..... 3

United States v. Larionoff,
431 U.S. 864 (1977)..... 6

Utter v. Hiraga,
845 F.2d 993 (Fed. Cir. 1988)..... 5

FEDERAL STATUTES

35 U.S.C. § 102(g) 3, 6

35 U.S.C. 135(a) 1, 6

35 U.S.C. § 282 3

REGULATIONS

37 C.F.R. § 1.633 ..... 4, 6

37 C.F.R. § 1.637 4

37 C.F.R. § 1.657(a) 3

49 Fed. Reg. 48,416 (Dec. 12, 1984) 5

OTHER

Comments on Standard for Declaring an Interference, available at http://www.uspto.gov/web/offices/dcom/bpai/rule/ab29.html 2

I. Introduction

The University of Washington ("UW") based its Opposition to Certiorari on the discretion accorded the PTO in 35 U.S.C. 135(a), not on the merits of the PTO's exercise of that discretion under the facts of this case or on the patentability of the claim the PTO awarded it. But it is the facial invalidity of UW's claim that highlights why the PTO overstepped its discretion here. As Judge Lourie stated in his dissent in the appeal below, the PTO's discretion "is cabined by the requirement that it not be exercised contrary to the statute under which the Director operates the PTO . . . ." App. 19. Indeed, the PTO has wandered from the Patent Statute by issuing two patents for one invention.

II. Argument

A. There Is an Overwhelming Public Interest That the PTO Hold an Interference So That Only One Valid Patent Is Issued for One Invention.

In its brief, UW asserted that there is no public interest in the "particularly unique" facts of this case. *See* UW Opp. at 22. But then UW asserted that, if an interference were held in this case, many other similar interferences would also have to be held, overwhelming the PTO. *See* UW Opp. at 18. UW cannot have it both ways - either Lilly's requested interference is of interest to patent owners or not. In fact, while the facts of this case are not so common as to overburden the PTO, patents are an integral part of the nation's economy, and there *is* overwhelming interest among patent owners and the public in the issuance of valid patents, particularly under the facts of this case.

Evidence of this public concern is found in the *amicus* briefs filed in support of Eli Lilly & Co. ("Lilly") on appeal. Although UW attempted to denigrate the *amici* who filed briefs in support of holding an interference, *see id.* at 12, two innovative companies, Genentech, Inc. and Guilford Pharmaceuticals, Inc., expressed their concern about the PTO's decision to issue two patents for one invention. These companies explained that they need to be confident that their earlier invented species claims will not be undermined by a party who later files a dominating genus claim.

In contrast to these *amicus* briefs, there were no briefs filed by any members of the public in support of UW or the PTO. Despite UW's arguments, it appears that there is no public concern about restricting the PTO's discretion to ensure compliance with the statutory scheme. Similarly, while UW cited two comments in support of the PTO's announcement of the "two-way test" in the Federal Register, *see* UW Opp. at 18-19, it failed to mention that there were seven comments filed opposing the "two-way test," including comments by groups representing many with an interest in a strong patent system, such as the Intellectual Property Owners Association and American Intellectual Property Law Association. *See* Comments on Standard for Declaring an Interference, *available at* http://www.uspto.gov/web/offices/dcom/bpai/rule/ab29.html. That UW concludes from this evidence there is no public concern about the issuance of two patents for one invention reveals an apparent attempt to divert attention from the real issues and facts of this case.

B. UW Has Never Defended Its Genus Claim or Explained How It Is Patentable Under the Patent Statute, But Instead Justifies the Federal Circuit's Decision Based on the PTO's Discretion

Despite the overwhelming public concern that the PTO issue valid patents, UW has never defended the validity of its broad patent claim. For that matter, neither the PTO nor the Federal Circuit ever explained how their decisions uphold the Patent Statute, which requires only one patent to be issued for each invention, and only to the first to invent. *See* 35 U.S.C. § 102(g). Instead of demonstrating the patentability of UW's broad claim, UW, like the PTO, has only invited Lilly to challenge its validity in district court, knowing the disadvantages Lilly would encounter there. *See* UW Opp. at 23 and App. at 64.

In fact, UW cannot defend the patentability of its broad claim, because without an interference the presumption of 37 C.F.R. § 1.657(a) provides that UW invented this genus claim after Lilly invented its species, and therefore is anticipated by Lilly's species. *See In re Slayter*, 276 F.2d 408 (C.C.P.A. 1960); *see also Titanium Metals Corp. of Am. v. Banner*, 778 F.2d 775, 781 (Fed. Cir. 1985).

UW argues that its claim is valid due to the mere fact that it was issued, *see* UW Opp. at 21, n. 12, but because its patent is involved in an interference, the presumption of validity under 35 U.S.C. § 282 does not apply. *See Lamont v. Berguer*, 7 U.S.P.Q.2d 1580, 1582 (Bd. Pat. App. & Int. 1988) ("Accordingly, the presumption of patent validity under 35 USC 282 which must be overcome by a party

charging invalidity is not applicable in interferences."). No other evidence of validity has ever been presented.

UW must be aware of the precarious status of its broad claim, though, and accordingly seems to have chosen to cloak itself in the discretion of the PTO for protection. As long as the PTO imposes a rigid "two-way test" and ignores the evidence of unpatentability before it, UW's genus claim is safe. But, if the PTO were to conduct an interference, UW's broad claim could be rendered invalid conclusively.

To maintain a distraction from these facts, UW has put forth several inaccuracies For instance, UW asserted that the PTO has used its discretion to adopt the "two-way test" to be "ensured that interferences would only be conducted in circumstances where there was no possibility of two patentable inventions." UW Opp. at 7; *see also id.* at 16. Such certainty is impossible under any circumstances, though, because the preliminary motions period in interferences, provided by 37 C.F.R. § 1.633 and § 1.637, allow patentees and applicants to modify the structure of the interference and the involved claims. As a result, it is *never* known when an interference is declared how it will proceed, including whether there is a strategy that the parties can use to salvage patents for themselves.

UW has also sought to distract this Court from the facial invalidity of its broad claim by its characterization of the history of this interference. UW emphasized Lilly's initial error in evaluating the specific genetic sequences claimed by the parties. *See* UW Opp. at 9 and 10, n. 5. Prior to the interference coming before the PTO, though, Lilly acknowledged this error, and has since not disputed that the species claims are separate inventions. Furthermore, in contrast to UW's characterization, *see* UW Opp. at 10, n.5,

Lilly requested an interference with UW's broad claim from the first time it alerted the Examiner to interfering subject matter, not just when it recognized that the species claims do not interfere. That UW presented such an undeservedly disparaging portrait of Lilly only highlights its attempts to avoid defending the merits of the patentability of its claim.

Finally, UW has presented an odd view of the history of the PTO's implementation of the "two-way test." For instance, UW cited the 1984 Notice of Rulemaking in 49 Fed. Reg. 48,416, 48,433 (Dec. 12, 1984), *see* UW Opp. at 6, and *Utter v. Hiraga*, 845 F.2d 993, 998 (Fed. Cir. 1988), *see* UW Opp. at 7, n.3, as evidence of the origin of a "two-way test." These references address "counts," tools used to compare the interfering claims, but not the interfering claims themselves. Because counts have never been at issue in this case, while the *claims* are, UW should have recognized that these proffered authorities are irrelevant.

Similarly, UW relied on *Chiong v. Roland*, 17 U.S.P.Q.2d 1541, 1544 (Bd. Pat. App. & Int. 1990), and *Hester v. Allgeier*, 687 F.2d 464, 465-67 (C.C.P.A. 1982), *see* UW Opp. at 6, n.7, but these cases are also irrelevant because in both a species claim was found to be separately patentable from a genus claim. UW has never been able to present a case where a "two-way test" was used to determine that a later filed genus claim was patentable in light of an earlier filed species claim.

In sum, UW's arguments only distract from the real issue of this case: Whether the PTO can refuse to determine the first inventor and instead issue a presumptively invalid and potentially dominating genus claim in a competing patent.

C. Despite UW's Use of Discretion as a Shield, the PTO Does Not Have Unlimited Discretion, But Must Abide by the Patent Statute as a Whole

UW denied that the Patent Statute, particularly 35 U.S.C. § 102(g), and the case law conflict with the PTO's exercise of discretion to issue two patents for one invention. *See* UW Opp. at 14 and 15. To conclude this, UW donned blinders and looked only at 35 U.S.C. § 135(a), proclaiming it to be "the only provision in the Patent Statute that addresses interferences." *Id.* at 14. UW cannot truly believe that 35 U.S.C. § 135(a) is the *only* provision of the Statute that applies when one is in interference. Surely, the other provisions of the Statute are not rendered void by an interference.

Indeed, as this Court held in *MCI Telecomm. Corp. v. American Tel. and Tel. Co.*, 512 U.S. 218, 229 (1994), and *United States v. Larionoff,* 431 U.S. 864, 873 (1977), Congress's intent in the statutory scheme as a whole must be adhered to when an agency acts. "When Congress gives an agency its marching orders, the agency must obey all of them, not merely some." *Public Citizen v. Nuclear Regulatory Comm'n,* 901 F.2d 147, 156 (D.C. Cir. 1990). And in fact, the PTO's own rules for interference proceedings specifically enable the parties to raise all patentability questions. *See* 37 C.F.R. § 1.633(a).

35 U.S.C. § 102(g) is not a discretionary provision of the Patent Statute. It must be heeded, regardless of other provisions that give the PTO discretion. Abiding by § 102(g) is not, as UW characterized it, picking and choosing among congressional enactments. It is one of a number of fundamental requirements imposed by the Statute on the

PTO, which the PTO must fulfill before issuing a patent. The statute has never been interpreted to require the PTO to use "extreme" means to find evidence not presented to it, as UW ridiculously suggested. *See* UW Opp. at 20. But at the same time the Statute cannot be interpreted to mean that the PTO can ignore evidence of unpatentability properly presented to it.

CONCLUSION

The public interest lies in having only valid patent claims issued by the PTO. To accomplish this, the PTO must abide by the Patent Statute in its entirety when exercising its discretion. Here, though, how issuance of UW's broad claim without an interference complies with the Statute has never been explained, but merely overlooked in UW's and the Federal Circuit's eagerness to accord the PTO discretion.

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